

**NHS Halton Clinical Commissioning Group
NHS Liverpool Clinical Commissioning Group
NHS St Helens Clinical Commissioning Group
NHS South Sefton Clinical Commissioning Group
NHS Southport and Formby Clinical Commissioning Group
NHS Warrington Clinical Commissioning Group**

Policy for Botulinum Toxin A & B

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”).

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).

Criteria from the <u>current</u> 2014/15 Cheshire and Merseyside commissioning policy	
Intervention	Botulinum Toxin A & B
Policy Statement	Restricted
Minimum eligibility criteria	<p>The use of botulinum toxin type A is commissioned in the following indications:</p> <ul style="list-style-type: none"> • Anal fissures only following a minimum of two months with standard treatment (lifestyle and topical pharmaceutical products) for chronic anal fissures that have not resulted in fissure healing; and only a maximum of 2 courses of injections. • Blepharospasm and hemifacial spasm. • Probable contracture of joint in multiple sclerosis, in conjunction with prolonged stretching modalities (i.e. in line with NICE Clinical Guideline 8). http://guidance.nice.org.uk/CG8 • Focal dystonia, where other measures are inappropriate or ineffective. • Focal spasticity in patients with upper motor neurone syndrome, caused by cerebral palsy, stroke, acquired brain injury, multiple sclerosis, spinal cord injuries and neurodegenerative disease, where other measures are inappropriate or ineffective. • Idiopathic cervical dystonia (spasmodic torticollis). • Prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at

Proposed criteria for the revised, future policy		High level summary of changes
Intervention	Botulinum Toxin A & B	
Policy Statement	Restricted	
Minimum eligibility criteria	<p><u>Botulinum Type B</u> The use of Botulinum toxin type B is not routinely commissioned.</p> <p><u>Botulinum Type A</u> Botulinum toxin type A is not routinely commissioned in the following indications:</p> <ul style="list-style-type: none"> • Canthal lines (crow's feet) and glabellar (frown) lines. • Any other indication that is not listed below. <p>The use of Botulinum type A is commissioned for the following indications and provided the eligibility criteria are met:</p> <p><u>Anal fissures</u></p> <ul style="list-style-type: none"> • Botulinum toxin type A is recommended as a treatment option in patients with chronic anal fissure that has not healed despite at least 8 weeks of topical management. <p>It has a similar mechanism of action to topical products. The preferred first line topical product is 0.4% glyceryl trinitrate (GTN) ointment, the only licensed non-surgical option available in the UK. Unlicensed topical 2% diltiazem cream and unlicensed topical 0.2% GTN ointment are alternatives if there has been a partial response to topical 0.4% GTN but intolerance such as headache has necessitated discontinuation.</p> <p>For patients who proceed to treatment with botulinum toxin type A and whose fissure has not healed after one course of injections, alternative options for on-going management should be considered. However, where the specialist determines there has been a partial response to the first course, a second</p>	<p>Reason for proposed change(s)</p> <p>See NICE Technology Appraisal 159 relating to the treatment of hyperhidrosis in people with social anxiety disorder: https://www.nice.org.uk/guidance/cg159</p> <p>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</p> <p>See NICE Technology Appraisal 260 relating to the treatment of migraines: https://www.nice.org.uk/guidance/ta260</p> <p>Impact of proposed change(s) Those who have severe</p>

<p>least 8 days are with migraine) that has not responded to at least three prior pharmacological prophylaxis therapies, and whose condition is appropriately managed for medication overuse (i.e. in line with NICE Technology Appraisal 260). http://guidance.nice.org.uk/TA260</p> <ul style="list-style-type: none"> • Refractory detrusor overactivity, only line with NICE Clinical Guideline 171 (women) http://guidance.nice.org.uk/CG171 and Clinical Guideline 97 (men) http://guidance.nice.org.uk/CG97 where conservative therapy and conventional drug treatment has failed to control symptoms. • Sialorrhoea (excessive salivary drooling), when all other treatments have failed. <p>Botulinum toxin type A is not routinely commissioned in the following indications:</p> <ul style="list-style-type: none"> • Canthal lines (crow's feet) and glabellar (frown) lines. • Hyperhidrosis. • Any other indication that is not listed above <p>The use of Botulinum Type B is not routinely commissioned.</p> <p>Where the use of botulinum toxin is used to treat an indication outside of the manufacturer's marketing authorisation, clinicians and patients should be aware of the particular governance requirements, including consent (which must be</p>	<p>course may be considered particularly for patients where surgery is less suitable.</p> <p>To assist with healing prevention of recurrence of fissures, patients should be encouraged to eat a high fibre diet and use laxatives if necessary.</p> <p>For the use of Botulinum toxin type A in treating Anal Fissures, refer also to the Pan Mersey Area Prescribing Committee Prescribing policy statement <i>BOTULINUM TOXIN Type A injection for chronic anal fissure:</i> https://www.panmerseyapc.nhs.uk/media/1568/botulinum_anal_201805_ps67_v0300.pdf</p> <p><u>Hyperhidrosis</u></p> <p>Botulinum toxin type A is recommended as a treatment option in patients with severe axillary hyperhidrosis that has not been adequately controlled by topical aluminium chloride or other extra-strength antiperspirants. Severe axillary hyperhidrosis is indicated by a baseline score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS).</p> <p>The first line treatment for primary axillary hyperhidrosis is aluminium chloride hexahydrate 20% solution, the only licensed non-surgical treatment currently available in the UK. Unlicensed or off label topical and oral treatments may be considered under specialist recommendation but there is weak evidence of their effectiveness.</p> <ul style="list-style-type: none"> • For patients who proceed to treatment with botulinum toxin type A and who do not have a clinical response after one treatment session, consider alternative options for on-going management. A clinical response is indicated by more than a 2 point improvement from baseline on the HDSS scale or more than a 4 point improvement from baseline on the Dermatology Life Quality Index (DLQI). • Botulinum toxin type A should not be offered to treat hyperhidrosis in people with social anxiety disorder - NICE CG159 (May 2013). 	<p>axillary hyperhidrosis (excessive underarm sweating) may now be eligible for treatment with botox.</p> <p>Those who have migraines may no longer be eligible for botox treatment if their condition is not responding to it well enough.</p> <p>EIA – The assessment did not identify any adverse impact on any protected group or impact on Human rights.</p>
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documented) for using drugs outside of their licensed indications.

For patients with conditions which are not routinely commissioned, as indicated above, requests will continue to be considered by Cheshire & Merseyside Clinical Commissioning Groups processes for individual funding requests, if there is evidence that the patient is considered to have clinically exceptional circumstances to any other patient experiencing the same condition within Cheshire & Merseyside. Requests to commission the use of botulinum toxin as an option to treat other indications, where a known cohort of patients can be identified, should be processed in accordance with the relevant CCG's defined processes.

If a subsequent CCG approved policy supersedes the information above, this section will be reviewed and updated.

For the use of Botulinum toxin type A in treating Hyperhidrosis, refer also to the Pan Mersey Area Prescribing Committee Prescribing policy statement ***BOTULINUM TOXIN TYPE A for Severe Axillary Hyperhidrosis*** https://www.panmerseyapc.nhs.uk/media/1067/botulinum_hidrosis_201507_p_s145_v0101.pdf

BOTULINUM TOXIN TYPE A is not routinely commissioned for non-axillary Hyperhidrosis.

Migraine
 Botulinum toxin type A is recommended as a treatment option for the prophylaxis of headaches in adults with migraine in accordance with **NICE TA 260** (June 2012).

NICE recommend Botulinum toxin type A as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine):

- that has not responded to at least three prior pharmacological prophylaxis therapies

AND

- whose condition is appropriately managed for medication overuse.

Treatment with botulinum toxin type A should be stopped in people whose condition:

- is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles)

OR

- has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months.

Botulinum toxin type A for the prophylaxis of migraine will be prescribed and administered under the supervision of a specialist designation neurological centre.

Botulinum Toxin A is also commissioned in the following indications:

		<p>Blepharospasm and hemifacial spasm</p> <p>Probable contracture of joint in multiple sclerosis, in conjunction with prolonged stretching modalities where other measures are inappropriate or ineffective (i.e. in line with NICE Clinical Guideline 186). https://www.nice.org.uk/guidance/cg186</p> <p>Focal dystonia, where other measures are inappropriate or ineffective.</p> <p>Focal spasticity in patients with upper motor neurone syndrome, caused by cerebral palsy, stroke, acquired brain injury, multiple sclerosis, spinal cord injuries and neurodegenerative disease, where other measures are inappropriate or ineffective.</p> <p>Idiopathic cervical dystonia (spasmodic torticollis).</p> <p>Refractory detrusor overactivity, only line with NICE Clinical Guideline 171 (women) http://guidance.nice.org.uk/CG171 (updated November 2015) and Clinical Guideline 97 (men) http://guidance.nice.org.uk/CG97 (updated June 2015) where conservative therapy and conventional drug treatment has failed to control symptoms and the patient is able and willing to self-catheterise.</p> <p>Sialorrhoea (excessive salivary drooling), when other treatments have failed.</p>	
		<p>Rationale</p> <p>Botulinum toxin can be used to treat various medical conditions and is an effective way to reduce pain and decrease muscle spasms. It is not commissioned for cosmetic reasons.</p>	
		<p>Evidence for inclusion and threshold</p> <p>NICE Technology Appraisal 159 relating to the treatment of hyperhidrosis in people with social anxiety disorder: https://www.nice.org.uk/guidance/cg159</p> <p>Pan Mersey Area Prescribing Committee (APC) Prescribing Policy Statement relating to the treatment of severe axillary hyperhidrosis: https://www.panmerseyapc.nhs.uk/media/1067/botulinum_hidrosis_201507_p_s145_v0101.pdf</p> <p>Pan Mersey Area Prescribing Committee (APC) Prescribing Policy Statement relating to the treatment of Chronic anal fissure:</p>	

		<p>https://www.panmerseyapc.nhs.uk/media/1568/botulinum_anal_201805_ps67_v0300.pdf</p> <p>NICE Technology Appraisal 260 relating to the treatment of migraines: https://www.nice.org.uk/guidance/ta260</p> <p>Spasticity in under 19s: management (CG145 Updated November 2015) https://www.nice.org.uk/guidance/cg145/chapter/1-guidance</p> <p>NHS Choices: Dystonia http://www.nhs.uk/conditions/dystonia/Pages/Introduction.aspx</p> <p>MHRA Report on Botox produced by Allergan (?) http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con108643.pdf</p> <p>Multiple sclerosis in adults: management, Clinical guideline [CG186] Published date: October 2014 https://www.nice.org.uk/guidance/cg186</p> <p>Refractory detrusor overactivity, only line with NICE Clinical Guideline 171 (women) http://guidance.nice.org.uk/CG171 (updated November 2015) and Clinical Guideline 97 (men) http://guidance.nice.org.uk/CG97 (updated June 2015)</p>	
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