

General Commissioning Policy

Treatment	Botulinum toxin type A
For the treatment of	Hyperhidrosis (excessive sweating)
Background	<p>Botulinum toxin type A is a high cost medicine, which is excluded from PbR-Tariff.</p> <p>There is limited evidence to support the use of botulinum toxin for the treatment of patients with severe axillary hyperhidrosis, but this is a potential alternative to surgery. However, it requires administration by appropriately skilled healthcare professionals and its long-term safety has yet to be established.</p> <p>There is no NICE Technology Appraisal of this product.</p> <p>All treatments requests should be submitted to the Hull CCG IFR panel for consideration.</p>
Commissioning position	<p>NHS Hull CCG will only commission the use of Botulinum toxin type A (Botox) when medically necessary for intractable, disabling focal primary hyperhidrosis, in cases where it has been demonstrated via the IFR submission that ALL of the following criteria are fulfilled:</p> <ol style="list-style-type: none"> 1. All lifestyle measures have been tried but have failed to resolve symptoms: avoiding identified triggers such as crowded rooms, caffeine, or spicy foods; frequent use of commercial antiperspirant (as opposed to a deodorant); avoiding tight clothing and manmade fabrics; wearing white or black clothing to minimize the signs of sweating and using dress shields to absorb excess sweat. 3. Topical aluminium chloride or other extra-strength antiperspirants are ineffective or result in a severe rash; <p>AND</p> <ol style="list-style-type: none"> 4. The patient is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (eg. anticholinergics, beta-blockers, or benzodiazepines) if sweating is episodic; <p>AND</p> <ol style="list-style-type: none"> 5. In appropriate patients a trial of iontophoresis* treatment has been unsuccessful. <p>AND</p> <ol style="list-style-type: none"> 6. Significant disruption of professional and / or social life has occurred because of excessive sweating. <p>(NB. In line with NICE recommendations, botulinum toxin is not commissioned for the treatment of hyperhidrosis (excessive sweating) in people with social anxiety disorder).</p> <p>Providing these criteria are met, the IFR Panel will approve a maximum of 2 treatments per year per patient to be commissioned, when used by an appropriately trained specialist (not for GP prescribing). If Botox treatment is approved, but more than two treatments per year are required, the specialist should re-submit an Individual Funding Request to Hull CCG for consideration.</p> <p>The treatment stopping criteria are:</p> <ul style="list-style-type: none"> ▪ Annual review ▪ Treatment should be discontinued if not tolerated or there is no

Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

	<p>objective evidence of response.</p> <p>[* Water iontophoresis is a non-invasive treatment where the hands / axillae are immersed in warm water, or a wet contact pad applied, through which a weak electric current is passed. A hospital trial of the treatment is offered on the NHS in York, usually consisting of 2– 4 sessions (of 20-30 mins) per week. Improvement usually occurs after 4–10 weeks, and where the hospital trial is positive, the patient has the option to purchase their own equipment and continue the treatment at home.]</p>
Effective from	September 2016
Summary of evidence / rationale	<p>Primary focal hyperhidrosis may affect the axillae (armpits), hands, feet, face, or scalp, and has no underlying cause</p> <p>Both Botox and Myobloc are neurotoxins produced by fermentation of the bacterium <i>Clostridium botulinum</i>. They interfere with neuromuscular transmission, temporarily paralysing the affected muscle. <i>Clostridium botulinum</i> is widely distributed in nature. Each strain produces one of eight antigenically distinct toxins designated A to H. Human disease is caused by types A, B, E, and (rarely) F. After repeated use of high doses, antibodies can develop in some individuals, making further treatment ineffective indefinitely.</p> <p>Some autonomic disorders (resulting in hypersecretion of glands) such as hyperhidrosis respond well to Botox, which is licensed for the treatment of axillary hyperhidrosis; botulinum toxin can also be helpful for palmar, plantar, and craniofacial hyperhidrosis but the procedure may be more difficult and painful at these sites, since Botulinum toxin is delivered by multiple intradermal injections to the affected areas.</p> <p>Adverse effects include compensatory sweating (5–10%) and injection-site pain or reactions (9–12%).</p> <p><i>Dosage regimes</i> - The marketing authorisation for Botox recommends that 50 Units is injected intradermally to each axilla, evenly distributed in multiple sites approximately 1-2 cm apart.</p> <p><i>Frequency of use</i> - The marketing authorisation for Botox states that repeat injections of axillary hyperhidrosis should be administered when effects from previous injections subside. Treatment response has been reported to persist for 4-7 months.</p> <p><i>NICE</i> – Only considered in CG159 “Do not offer botulinum toxin to treat hyperhidrosis (excessive sweating) in people with social anxiety disorder. This is because there is no good-quality evidence showing benefit from botulinum toxin in the treatment of social anxiety disorder and it may be harmful.”</p> <p><i>SMC</i> – not considered</p> <p><i>Drug & Therapeutics Bulletin 2005</i> -There is some evidence to support the use of botulinum toxin for the treatment of patients with severe axillary hyperhidrosis, and this is a potential alternative to surgery. However, it is expensive, requires administration by appropriately skilled healthcare professionals and its long-term safety has yet to be established.</p>
Date	May 2017
Review date	May 2019
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References:

1. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology Naumann et al. *Neurology*. 2008 May 6; 70(19):1707-14. <http://www.ncbi.nlm.nih.gov/pubmed/18458231>

2. NICE Clinical knowledge summary – Hyperhidrosis <http://cks.nice.org.uk/hyperhidrosis>
3. Guidelines for the primary care treatment and referral of focal hyperhidrosis [Lowe et al, 2003] http://www.eguidelines.co.uk/eguidelinesmain/gip/media/pdfs/Full_hh_guideline.pdf
4. Naumann, & Lowe,(2001) Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomised, parallel group, double blind, placebo controlled trial *BMJ* 2001;323:596 <http://www.bmj.com/content/323/7313/596.pdf%2Bhtml>
5. DTB. Treatments for excessive armpit sweating. *Drug & Therapeutics Bulletin* 2005;43 (10):77-80. <http://dtb.bmj.com/content/43/10/77.abstract>
6. NICE Clinical Guideline (May 2013) Social anxiety disorder: recognition, assessment and treatment (CG159) <https://www.nice.org.uk/guidance/cg159>