NHS
Vale of York
Clinical Commissioning Group

COMMISSIONING POLICY RECOMMENDATION
TREATMENT ADVISORY GROUP
Policy agreed by (*Vale of York CCG/date*)

Drug, Treatment, Device name		
Botulinum toxin type A (Botox, Allergan; and all other brands)		
Licensed indication		
Hyperhidrosis (excessive sweating)		
Cost per patient (at recommended dose)		
Botox 100unit vial	50 units to be injected into each axilla evenly distributed in multiple sites approximately 1-2 cm apart. Clinical improvement generally occurs within the first week after injection. Repeat injection of BOTOX can be administered when the clinical effect of a previous injection diminishes and the treating physician deems it necessary. Treatment response has been reported to persist for 4-7 months. Injections should not be repeated more frequently than every 16 weeks	£138.20
Resource impact on population		
Botulinum toxin type A is a high cost medicine, which is excluded from PbR-Tariff. It is frequently requested for use in secondary care but there is variation in funding across the region. 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.		
Recommendation to Routinely Commission **OR** **Not Routinely Commission** **OR** **Commission under criteria**		
When is funding appropriate?		
Botulinum toxin type A (brands licensed for this indication only) is routinely funded under the following circumstances ▪ when medically necessary for intractable, disabling focal primary hyperhydrosis, that has not been adequately controlled by topical aluminium chloride/other extra-strength antiperspirants; AND patient is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines) if sweating is episodic ▪ where excessive sweating has caused demonstrable disruption of professional and/or social life ▪ for a maximum of 2 doses per year per patient ▪ when used by an appropriately trained specialist (not for GP prescribing)		
Clinical and cost effectiveness evidence		

Background
Hyperhidrosis is defined as focal, visible, excessive sweating of at least 6 months duration without apparent cause with at least one episode per week, impairs daily activities, age of onset of less than 25 years, positive family history and cessation of focal sweating during sleep. Botulinum toxin is injected into the skin blocking the release of acetylcholine from overactive cholinergic sudomotornerve fibres. The majority of patients will require ongoing treatment. The treatment algorithm produced by the International Hyperhidrosis Society consider Botulinum Toxin as a second line therapy.

Dosage regimes
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.

Frequency of use
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.

NICE – Not considered SMC – not considered

Drug & Therapeutics Bulletin 2005
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.

Bandolier
"It does appear, though, that botulinum toxin reduces symptoms in this rare condition. The report of increased palmer sweating in patients with axillary hyperhidrosis should be noted and it was not reported in the trial whether this subsided as the effects wore off.
…It does not provide a cure and repeated injections would be required to limit symptoms in the long term."

Specialist responsibilities – Prescribing, disease and drug monitoring remains the responsibility of the specialist.

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.

NICE Clinical knowledge summary – Hyperhydrosis http://cks.nhs.uk/hyperhidrosis

Guidelines for the primary care treatment and referral of focal hyperhidrosis
http://www.eguidelines.co.uk/eguidelinesmain/gip/media/pdfs/Full_hh_guideline.pdf

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

Abstract

Objectives: To evaluate the safety and efficacy of botulinum toxin type A in the treatment of bilateral primary axillary hyperhidrosis.

Design: Multicentre, randomised, parallel group, placebo controlled trial.

Setting: 17 dermatology and neurology clinics in Belgium, Germany, Switzerland, and the United Kingdom.

Participants: Patients aged 18-75 years with bilateral primary axillary hyperhidrosis sufficient to interfere with daily living. 465 were screened, 320 randomised, and 307 completed the study.

Interventions: Patients received either botulinum toxin type A (Botox) 50 U per axilla or placebo by 10-15 intradermal injections evenly distributed within the hyperhidrotic area of each axilla, defined by Minor's iodine starch test.

Main outcome measures: Percentage of responders (patients with ≥50% reduction from baseline of spontaneous axillary sweat production) at four weeks, patients' global assessment of treatment satisfaction score, and adverse events.

Results: At four weeks, 94% (227) of the botulinum toxin type A group had responded compared with 36% (28) of the placebo group. By week 16, response rates were 82% (198) and 21% (16), respectively. The results for all other measures of efficacy were significantly better in the botulinum toxin group than the placebo group. Significantly higher patient satisfaction was reported in the botulinum toxin type A group than the placebo group (3.3 v 0.8, P<0.001 at 4 weeks). Adverse events were reported by only 27 patients (11%) in the botulinum toxin group and four (5%) in the placebo group (P>0.05).

Conclusion: Botulinum toxin type A is a safe and effective treatment for primary axillary hyperhidrosis and produces high levels of patient satisfaction.

Place in therapy relative to available treatments

This should be used in patients inadequately controlled by topical aluminium chloride/ other extra-strength antiperspirants; AND patient is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (eg anticholinergics, betablockers or benzodiazepines). This should be used prior to consideration of surgery.

Patient safety / pharmacovigilance

The most frequently reported adverse events (3-10% of adult patients) following injection of Botox® in double-blind studies included injection site pain and haemorrhage, non-axillary sweating (compensatory sweating), infection, pharyngitis, flu syndrome, headache, fever, neck or back pain, pruritus, and anxiety .

When to stop treatment	
Stopping criteria: ▪ Annual review Treatment should be discontinued if not tolerated or no objective evidence of response	
Who prescribes?	
It should only be prescribed by secondary care clinicians with appropriate training and experience in administering botulinum toxin. It is not to be prescribed by GPs.	
Stakeholder views	
Equity of access	
SPECIFICATION DATE, REVIEW DATE, AND LEAD NAME/JOB TITLE	
Origin Date: November 2013	Originator:
TAG Review Date:	Stuart Kerr/ Chris Ranson
TAG Recommendation Date:	