South East London Area Prescribing Committee
Formulary recommendation

Reference	**049**
Intervention:	**Botulinum toxin type A injection for the treatment of hypersalivation** (Botulinum toxin is a protein complex derived from the bacterium *Clostridium botulinum*)
Date of Decision	**May 2016**
Date of Issue:	**June 2016**
Recommendation:	**RED – suitable for prescribing and supply by hospital only**
Further Information	• Botulinum toxin is accepted for use in SEL for the treatment of hypersalivation if the following criteria are fulfilled: (i) Treatment with antimuscarinic medicines (such as hyoscine) is contraindicated, not tolerated or clinically ineffective AND (ii) The patient has a drooling severity and incidence scale score of ≥7 AND (iii) Surgical treatment is not appropriate for the patient • A total dose of 50-60 units will be used for the first treatment and for subsequent treatments this will be titrated according to response to a maximum 100 units total dose. • The injection is usually administered into the parotid and sub-mandibular glands bilaterally. The dose injected into the submandibular glands is lower than the dose injected into the parotid glands. • Treatment effectiveness is measured using the drooling severity and incidence scale. Treatment with botulinum toxin type A injection will be stopped if it is ineffective after the first dose. • Where treatment is effective (a score of ≤6 achieved), treatment with botulinum toxin type A injection may be repeated at a minimum of 4 monthly intervals. • Botulinum toxin type A injection is a tariff excluded, CCG commissioned medicine for this indication and will be classified as a B* medicine locally. • A **B* notification form** will need to be completed and submitted to commissioners for each patient treated with botulinum toxin for hypersalivation in order for the cost of the medicine to be reimbursed to the Trust. • Only the most cost effective brand of botulinum toxin type A injection will be commissioned for use in this indication, taking into consideration any negotiated prices. • **Note:** At the time of writing there are no brands of botulinum toxin type A injection licensed for the treatment of hypersalivation and patients should be made aware of this before treatment is started.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• It is estimated there will be up to 30 patients per year eligible for treatment in SEL. • Assuming treatment is with the most cost effective brand (currently Xeomin®), the cost of treatment with100 units every 4 months per patient per year (3 injections/ patient/year/) would be £288 (including VAT). • This would result in a total cost across SEL of approximately £8,700 per year. • This does not include activity related costs from the appointments needed to administer the injections. However, some of the overall spend will be offset by a reduction in the use of antimuscarinic medicines.

Usage Monitoring & Impact Assessment	Acute Trusts: • Monitor usage and report back to APC when required. • Audit use as required by commissioners to ensure use is in line with this recommendation.
	CCGs: • Monitor monthly tariff excluded high cost drugs invoicing submitted by Trusts to the South East CSU to ensure billing of most cost effective product.
Evidence reviewed	**References (from evidence review)** 1. Vashishta R, Nguyen S, White D et al. Botulinum toxin for the treatment of sialorrhea: a meta-analysis. Otolaryngology Head and Neck Surgery 2013 **148** (2) p191-196 2. Drug-induced hypersalivation – what treatment options are available? UKMi Q&A 54.8 November 2015 3. Blasco P, Allaire J. Drooling in the developmentally disabled: management practices and recommendations. Developmental Child Neurology. 1992 **34** p849-862 4. Lakraj A, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. Toxins 2013 5 (5) p1010-1031 5. Squires N, Wills A, Rowson J. The management of drooling in adults with neurological conditions. Current opinioins in otolaryngology Head and Neck Surgery 2012 (20) p171-176. 6. Thomas-Stonell N, Gtreenberg J. Three treatment approaches and clinical factors in the reduction of drooling. Dysphagia 1988 **3** p73-78. 7. Reid S, Johnson H, Reddihough D. The drooling impact scale: a measure of the impact of drooling in children with developmental disabilities. Developmental Medicine and Child Neurology 2010 **52** p23-28 8. Rapp D. Management of drooling. Developmental Medicine and Child Neurology 1988 **30** p128-129. 9. Summary of Product Characteristics: Botox 100 units. Available online at: http://www.medicines.org.uk/emc/medicine/112 <accessed on 05/02/2016> 10. Lim M, Mace A, Reza Nouraei S et al. Botulinum toxin in the management of sialhorrea: a systematic review. Clinical Otolaryngology 2006 **31** p267-272 11. Database of Abstracts of Reviews of Effects: Quality assessed reviews 2014: Lim M et al. Botulinum toxin in the management of sialhorrea: a systematic review. Available online at: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0022759/ <accessed 07/02/2016> 12. Rodwel K, Edwards P, Ware R et al. Salivary gland botulinum toxin injections for drooling in children with cerebral palsy and neurodevelopmental disability: a systematic review. Developmental Medicine and Child Neurology 2012 **54** p977-987. 13. Jongerious P, van den Hoogen F, van Limbeek J et al. Effect of botu,inum toxin in the treatment of drooling: a controlled clinical trial. Pediatrics 2004 **114** p620-627. 14. Scheffer A, Erasmus C, van Hulst K et al. Botulinum toxin versus submandibular duct relocation for severe drooling. Developmental Medicine and Child Neurology 2010 **52** p1038-1042. 15. George K, Kiani H, WItherow H. Effectiveness of botulinum toxin B in the treatment of drooling. British Journal of Oral and Maxillofacial Surgery 2013 **51** p783-785. 16. Young C, Johnson E, Sathasivam S et al. Treatment for sialorrhea (excessive saliva) in people with motor neuron disease/amyotrophic lateral sclerosis. Cochrane Database of Systematic Reviews May 2011

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.

b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**