South East London Area Prescribing Committee
Formulary recommendation

Reference	**051**
Intervention:	**Botulinum toxin type A injection for the treatment of myofascial pain syndrome associated with temporomandibular jaw dysfunction (TMJD)** (Botulinum toxin is a protein complex derived from the bacterium *Clostridium botulinum*)
Date of Decision	**August 2016**
Date of Issue:	**September 2016**
Recommendation:	**RED – suitable for prescribing, supply and administration by hospital only**
Further Information	• Botulinum toxin is accepted for use in SEL for the treatment of severe, chronic myofascial pain syndrome (MPS) associated with TMJD if the following criteria are met: (i) The MPS results in soft / liquid diet and disturbs sleep **AND** (ii) The patient does not respond to the following standard treatments over a period of at least 3 months: soft bite raising appliance (jaw splints), NSAIDs and jaw exercises **AND** (iii) The patient's pain is not improving based on a pain perception visual analogue scale (determined case by case through clinician review). • Botulinum toxin A is administered in aliquots into different areas of the affected trigger points of the temporo-mandibular and masseter muscles. • Treatment effectiveness will measured through clinician review of patient outcomes: – Reduction in pain (measured through a visual analogue scale) AND – Reduction in the use of analgesics and associated side effects AND – Improvement in diet and reduction in the use of dietetic products AND – Improvement in sleep • Treatment with botulinum toxin type A will be stopped if ineffective after the first dose. • Where treatment is effective, treatment with botulinum toxin type A injection may be repeated at a minimum of 3 to 4 monthly intervals. • As effectiveness of boutulinum toxin A diminishes with repeat dosing, only a maximum of **4** treatments (3 to 4 months apart) will be commissioned. • This recommendation **does not** cover the use of botulinum toxin in the atypical facial pain variant of TMJDS. An algorithm outlining the place in therapy of botulinum toxin A in the management of TMJD has been developed by local dental specialists. This notes the use of amitriptyline will be reserved for patients with the atypical facial pain variant of TMJDS. • Botulinum toxin type A injection is a tariff excluded, CCG commissioned medicine and will be classified as a B* medicine locally for use in MPS associated with TMJD. • A **B* notification form** will need to be completed and submitted to commissioners for each patient treated with botulinum toxin for MPS associated with TMJD 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 MPS associated with TMJD 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 64 patients per year eligible for treatment in SEL. • Assuming treatment is with the most cost effective brand based on negotiated prices: – The cost of administering a total treatment dose of 100 units every 3 months per patient per year would be £384 (including VAT; based on price of Xeomin®). – This would result in a total cost across SEL of approximately £25,500 pa. • This does not include activity related costs from the appointments needed to administer the injections. However, specialists have estimated that outpatient appointments will reduce as the appointment intervals will increase from 2 monthly to 3 monthly.
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. NICE Clinical Knowledge Summaries (CKS): TMJ disorders. Available online (accessed on 10/05/2016) 2. Commissioning Guide: Temporomandibular Joint Disorders. British Association of Oral and Maxillofacial Surgeons 2014. 3. Interventional Procedure Guidance (IPG) 500: Total Prosthetic Replacement of the Temporomandibular Joint. National Institute for Health and Care Excellence 2014. Available online (accessed on 10/05/2016) 4. Temporomandibular Disorders (TMDs): an update and management guidance for primary care from the UK Specialist Interest Group in Orofacial Pain and TMDs (USOT). Faculty of Dental Surgery 2013 5. Fallah H, Currimbhoy S. Use of Botulinum Toxin A for Treatment of Myofascial Pain and Dysfunction. Journal of Oral Maxillofacial Surgery 2012 **70** 1243-1245. 6. Bihari K. Safety, effectiveness and duration of effect of Botox after switching from Dysport for blepharospasm, cervical dystonia and hemifacial spasm. Current Medical Research Opinion 2005 **21** (3) p433-438. 7. Summary of Product Characteristics: Dysport. Available online (accessed on 10/05/2016) 8. Von Lindern J, Niederhagen B, Berge S. Type A Botulinum Toxin in the Treatment of Chronic Facial Pain Associated With Masticatory Hyperactivity. Journal of Pral and Maxillofacial Surgery 2003 **61** p774-778. 9. Nixdorf D, Heo G, Major P. Randomised controlled trial of botulinum toxin A for chronic myogenous orofacial pain. Pain 2002 **99** p465-473 10. Ernberg M et al. Efficacy of botulinum toxin type A for treatment of persistent myofascial TMD pain: A randomised, controlled, double-blind multicenter study. Pain 2011 **152** p1988-1996 11. Kurtuglu C, Gur O, Kurcku M et al. Effect of Botulinum Toxin A in Myofascial Pain Patients With or Without Function Disc Displacement. Journal of Oral Maxillofacial Surgery 2008 **66**: p1644-1651 12. Sidebottom A, Patel A, Amin J. Botulinum injection for the management of myofascial pain in the masticatory muscles. A prospective outcome study. British Journal of Oral and Maxillofacial Surgery 2012. Available online (accessed 10/05/2016) 13. Freund B, Schwartz M, Symington M. Botulinum toxin: new treatment for temporomandibular disorders. British Journal of Oral and Maxillofacial Surgery 2000 **38** p466-471. 14. Freund B, Schwartz M. Temporal Relationship of Muscle Weakness and Pain Reduction in Subjects Treated with Botulinum Toxin A. The Journal of Pain 2003 **4** (3) p159-165 15. Freund B, Schwartz M, Symington J. The Use of Botuluinum Toxin for Treatment of Temporomandibular Disorders: Preliminary Findings. Journal of Oral and Maxillofacial Surgery 1999 **57** p916-920 16. British National Formulary 71

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.**