South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation

Reference	**129**
Intervention:	**Botulinum toxin type A injection for intraprocedural use in hand surgery during surgical neurolysis in adults. (Single injection as an adjuvant treatment.)** (Botulinum toxin is a protein complex derived from the bacterium *Clostridium botulinum*)
Date of Decision	**September 2021**
Date of Issue:	**October 2021**
Recommendation:	**RED – suitable for prescribing, supply and administration by hospital only (GSTfT is the centre that will carry out this procedure)**
Further Information	• Botulinum toxin type A injection, as a **single injection**, is accepted for use in SEL as a **last line** adjuvant treatment option for hand pain that is neuropathic in origin **and** has failed to respond to conventional pharmacological, psychological and physical interventions. The injection is administered directly to the nerve during surgical neurolysis. • Patients will have exhausted all other conventional treatment options under their specialist pain team and will have been referred to the plastic surgery team at Guy's and St. Thomas' NHS Foundation Trust (GSTfT) for surgical neurolysis. This includes patients with: - Nerve injury to the hand that has previously been surgically repaired but with poor outcome resulting in nerve pain and - Complex regional pain syndrome in the hand secondary to trauma, for example a fracture or blunt injury or ischemic injury. • Conventional treatments for neuropathic pain are outlined in the local guideline for managing neuropathic pain in primary care, the local specialist treatment guideline for refractory neuropathic pain and the NICE guideline on the management of neuropathic pain. • A dose of 50 to 100 units will be delivered as a single injection for intraprocedural use during hand surgery as surgical neurolysis with bupivacaine 0.5%. • Use of botulinum toxin type A injection in this setting is **restricted** to the regional plastic surgery service at GSTfT only. • Outcomes from treatment are measured using a pre- and post-operative visual analogue scale and the Disabilities of the Arm, Shoulder and Hand (DASH) score. • Botulinum toxin type A injection has been designated as a high-cost drug excluded from the national tariff. Treatment with botulinum toxin type A injection is only commissioned in line with this formulary recommendation. • Only the most cost-effective brand of botulinum toxin type A injection will be commissioned for use, 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 neuropathic pain and administration into the nerve is not licensed. 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	• The applicant estimates that up to a total of 4 patients per year may be eligible for treatment at the tertiary plastic surgery centre at GSTfT. • Assuming treatment is with the most cost-effective brand (currently Xeomin®, 100 units), the cost of treatment for 4 patients every year would be ~£400 per year. • This does not include activity related costs from the appointments needed to administer the injections. However, as the injection is administered during an existing procedure, use in this setting is not expected to increase activity.

Usage Monitoring & Impact Assessment	**Acute Trusts:** • The service may be requested by the SEL IMOC to provide clinical audit data to demonstrate outcomes from botulinum toxin type A injection in this setting and compliance with the criteria in this recommendation.
	SEL CCG borough Medicines Optimisation teams: • Monitor monthly tariff excluded high cost drugs invoicing submitted by Trusts to the CSU to ensure billing of most cost effective product.
Evidence reviewed	**References (from evidence review)** 1) 2020. Introduction: Neuropathic pain in ADULTS: PHARMACOLOGICAL management in non-specialist settings: NICE Guidance Available here. [Accessed September 7, 2021]. 2) Backonja, M.-M., 2003. Defining neuropathic pain. Anesthesia & Analgesia, 97(3), pp.785–790. 3) 2019. SEL Pharmacological Management of Neuropathic Pain in Adults in primary care. Available here. [Accessed September 7, 2021]. 4) 2021. Xeomin 200 Units powder for solution for injection. Xeomin 200 units powder for solution for injection - Summary of Product Characteristics (SmPC) - (emc). Available here: [Accessed September 7, 2021]. 5) Jeynes, L.C. & Gauci, C.A., 2008. Evidence for the use of botulinum toxin in the chronic pain setting—a review of the literature. Pain Practice, 8(4), pp.269–276. 6) Finnerup, N.B., Attal, N. & Haroutounian, S., 2015. Pharmacotherapy for neuropathic pain in adults: systematic review, meta-analysis and updated NeuPSIG recommendations. Lancet Neurol, 14(2), pp.162–173 7) Egeo, G., Fofi, L. & Barbanti, P., 2020. Botulinum neurotoxin for the treatment of neuropathic pain. Frontiers in Neurology, 11, pp.1–15. 8) Attal, N. et al., 2016. Safety and efficacy of Repeated injections of botulinum TOXIN A in peripheral neuropathic pain (BOTNEP): A randomised, double-blind, placebo-controlled trial. The Lancet Neurology, 15(6), pp.555–565. 9) Bello RJ, Cooney CM, Melamed E, et al. The therapeutic efficacy of botulinum toxin in treating scleroderma-associated Raynaud's phenomenon: a randomized, double-blind, placebo-controlled clinical trial. Arthritis Rheumatol. 2017;69(8):1661e1669 10) Motegi SI, Uehara A, Yamada K, et al. Efficacy of botulinum toxin Bb injection for Raynaud's phenomenon and digital ulcers in patients with systemic sclerosis. Acta Derm Venereol. 2017;97(7): 843e850. 11) Neumeister MW, Chambers CB, Herron MS, et al. Botox therapy for ischemic digits. Plast Reconstr Surg. 2009;124(1):191e201. 12) Uppal L, Dhaliwal K, Butler P. A prospective study of the use of botulinum toxin injections in the treatment of Raynauds syndrome associated with scleroderma. Journal of Hand Surgery 2014 39 p876-880. 13) Neumeister MW. Botulinum toxin type a in the treatment of Raynaud's phenomenon. J Hand Surg Am. 2010;35(12):2085e2092. 14) Motegi S, Yamada K, Toki S, et al. Beneficial effect of botulinum toxin A on Raynaud's phenomenon in Japanese patients with systemic sclerosis: a prospective, case series study. J Dermatol. 2016;43(1):56e62. 15) Zhang X, Hu Y, Nie Z, et al. Treatment of Raynaud's phenomenon with botulinum toxin type A. Neurol Sci. 2015;36(7):1225e1231. 16) Lessard L, Bartow M, Lee J et al. Botulinum toxin A: A novel therapeutic modality for upper extremity chronic regional pain syndrome. Plast Reconstr Surg Glob Open 2018 Oct 16;6(10):e1847. 17) Larrakkar A, Borah G. Botulinum Toxin A Salvage of Ischemic Hand Trauma. Plast Reconstr Surg . 2020 Jan;145(1):161-164. 18) Ovens L, Dewar D. Use of botulinum toxin in complex regional pain syndrome of the hand. European Journal of Plastic Surgery 2013 36 p37-39. 19) MHRA, 2014. Botulinum toxin products: Rare but serious risks. Botulinum toxin products: rare but serious risks. Available here. [Accessed September 7, 2021].

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.
b) This SEL IMOC 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