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

Reference	**119**
Intervention:	**Botulinum toxin type A via intramuscular injection into vocal cords for spasmodic dysphonia (laryngeal dystonia) in adults** (Botulinum toxin is a protein complex derived from the bacterium *Clostridium botulinum*)
Date of Decision:	**November 2020**
Date of Issue:	**December 2020**
Recommendation:	**Red – suitable for prescribing, supply and administration by the hospital only (GSTfT is the specialist tetiary centre providing this service)**
Further Information:	· Botulinum toxin type A injection is accepted for use in SEL for the treatment of spasmodic dysphonia (laryngeal dystonia) in adults in line with the following criteria: - The spasmodic dysphonia is interfering with function or independence (e.g. communication, ability to intake nutrition) and/or is painful, **and** - Conservative measures (including at least 3 sessions of speech therapy) have been ineffective and the next step would otherwise be surgery. · The applicant is required to ensure that there is robust governance in place at Trust level for the use of botulinum toxin type A in this setting. This includes developing a clinical guideline for approval through the Trust Drug and Therapeutics Committee. The guideline should set out the place in therapy and outline how outcomes will be monitored over time. The guideline will also be shared with the SEL IMOC for information. · In line with information provided by the applicant, a dose of botulinum toxin type A of 1.5 to 3 units will be injected into each vocal cord at each visit. Depending on patient response, treatment will be repeated 3-6 monthly if successful. · The SEL IMOC requests the applicant to collate and report data back to the Committee in 12 months outlining: - The total numbers of patients treated with botulinum toxin type A for spasmodic dysphonia - Whether use is in line with this recommendation - Patient related outcomes, including (i) Response to treatment [to include QoL and the voice handicap index] (ii) adverse effects (iii) the number of patients stopping treatment · Botulinum toxin type A injection is a tariff excluded, CCG commissioned medicine for this indication and with respect to the local high cost drugs policy, will be classified as a B* medicine locally. · Only the most cost-effective brand of botulinum toxin type A injection will be commissioned for use in this indication, taking into account any locally negotiated prices. · **Note:** at the time of writing, there are no brands of botulinum toxin type A injection licensed for the treatment of spasmodic dysphonia. Patients should be made aware of the off-label nature of use before treatment is started.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	· This application suggests 15 patients per year will be treated in SEL. The patient number will be cumulative over time. · Based on costs of the botulinum toxin type A preparation with the lowest acquisition cost and the cost of ENT initial and follow up clinical attendances, a cost of between £3,360-£6,720 for the first year in SEL. If all patients remained on treatment, by 5 years the patient cohort would have reached 75, which would equate to £16,800 - £33,600 per annum costs in SEL or up to ~£1,800 per 100,000 population. Of this, £9,000 to £18,000 would be drug costs (up to £1,000 per 100,000 population).

Usage Monitoring & Impact Assessment	**Trusts:** · Monitor use and submit usage data and audit reports (against this recommendation and the pathway) upon request to the SEL IMOC. · The report requested after 1 year should be collated and presented to the Committee no later than February 2022.
	SEL CCG Borough Medicines Teams: · Monitor tariff excluded high cost drugs invoicing submitted by the Trust to the CSU to ensure billing of the most cost effective product.
Evidence reviewed:	**References (from evidence evaluation)** 1. Watts C, Whurr R, Nye C. Botulinum toxin injections for the treatment of spasmodic dysphonia. Cochrane Database of Systematic Reviews. 2004. 2. Stachler R, Francis D. Schwartz S et al. Clinical Practice Guideline: Hoarseness (Dysphonia(update. Otolaryngology–Head and Neck Surgery 2018 Volume: 158 issue: 1_suppl, page(s): S1-S42. 3. Botox (botulinum toxin). Summary of Product Characteristics. Available online at https://www.medicines.org.uk/emc/product/859/smpc (accessed 10/02/2020). 4. Truong D, Rontal M, Rolnick M, Aronson A, Mistura K. Double-Blind Controlled Study of Botulinum Toxin in Adductor Spasmodic Dysphonia. The Laryngoscope. 1991;101(6):630-634. 5. Finnegan E, Luschei E, Gordon J, Barkmeier J, Hoffman H. Increased Stability of Airflow Following Botulinum Toxin Injection. The Laryngoscope. 1999;109(8):1300-1306. 6. van Esch B, Wegner I, Stegeman I, Grolman W. Effect of Botulinum Toxin and Surgery among Spasmodic Dysphonia Patients: A Systematic Review. Otolaryngology–Head and Neck Surgery. 2016;156(2):238-254. 7. Patel P, Kabagambe E, Starkweather J, Keller M, Gamsarian V, Lee J et al. Outcomes of Onabotulinum Toxin A Treatment for Adductor Spasmodic Dysphonia and Laryngeal Tremor. JAMA Otolaryngology–Head & Neck Surgery. 2018;144(4):293. 8. Boutsen F, Cannito M, Taylor M, Bender B. Botox Treatment in Adductor Spasmodic Dysphonia. Journal of Speech, Language, and Hearing Research. 2002;45(3):469-481. 9. Venkatesan N, Johns M, Hapner E, DelGaudio J. Abductor paralysis after botox injection for adductor spasmodic dysphonia. The Laryngoscope. 2010;1177-1180

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