General Commissioning Policy

Treatment	**Botulinum toxin type A (Botox® / Dysport®)**
For the treatment of	**Spasmodic Dysphonia**
Background	This commissioning policy is needed because although Botox and Dysport are licensed for the treatment of certain focal dystonias, the limited evidence base for the efficacy of Botulinum A injections in spasmodic dysphonia means the treatment is not currently routinely commissioned and requests are thus considered via the Individual Funding Request (IFR) process.
Commissioning position	NHS Hull Clinical Commissioning Group (CCG) will consider commissioning Botox injections into the vocal cords of patients in whom: Spasmodic dysphonia has been diagnosed by a Consultant Otolaryngologist (and a more generalised dystonia has been ruled out by a Consultant Neurologist) Speech and language therapy has not adequately improved the voice quality The resulting communication difficulties are interfering significantly with daily living and adversely affecting the patient's quality of life.
Effective from	September 2016
Summary of evidence / rationale	Spasmodic Dysphonia (SD) [or laryngeal dystonia] is a voice disorder caused by involuntary laryngeal muscle spasms giving strained and stuttering speech. Patients demonstrate increased tone or tremor of the intralaryngeal muscle groups responsible for either opening (abductor SD) or closing (adductor SD) of the vocal folds. Patients with SD suffer social isolation, depression, and reduced Quality of Life, comparable to impairments observed in patients with congestive heart failure, angina, and chronic obstructive pulmonary disease. The recommendations of the American Academy of Otolaryngology (AAO) in their clinical practice guideline for Dysphonia (Ref 1) are based on a few controlled trials, some diagnostic studies with minor limitations, and overwhelmingly consistent evidence from observational studies. Intramuscular injection of botulinum toxin into the affected muscles causes transient paralysis of these muscles by inhibiting neurotransmission, thus reducing the spasm and controlling symptoms for 3 to 6 months after treatment (Stong 2005). Treatment can be performed on awake, ambulatory patients with minimal discomfort. The AAO Guideline states "a large body of evidence supports the efficacy of botulinum toxin A for treating adductor SD. Multiple double-blind, randomized, placebo controlled trials of botulinum toxin for adductor SD using both self-assessment and expert listeners found improved voice in patients treated with Botulinum toxin injections". (Troung 1991, Cannito

Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

	2004) Botulinum toxin treatment has also been shown to improve self-perceived dysphonia, mental health, and social functioning (Courey 2000). A meta-analysis concluded that botulinum toxin treatment of spasmodic dysphonia results in "moderate overall improvement;" however, it notes concerns of methodological limitations and lack of standardization in assessment of botulinum toxin efficacy and recommends caution when making inferences regarding treatment benefit (Boutsen 2002). Despite these limitations, among laryngologists, botulinum toxin is considered the "treatment of choice" for adductor SD (Soulica 2004, Stong 2005, Watts 2004). The Watts paper was a Cochrane systematic review (Ref 10) of all RCTs in which botulinum toxin was compared to an alternative treatment, placebo or non-treated control group. Only one study met the inclusion criteria (Troung 1991) and found improvement in voice function in patients with adductor spasmodic dysphonia. It was the only study which reported a treatment/no treatment comparison. It reported significant beneficial effects for fundamental frequency, range, spectrographic analysis, independent ratings of voice severity and patient ratings of voice improvement. This suboptimal evidence led the Cochrane review to conclude that: "The lack of supporting evidence from RCTs results in an inability to draw unbiased generalized conclusions regarding the effectiveness of botulinum toxin for all types of spasmodic dysphonia". The AAO guideline states that botulinum toxin injections have a good safety record. Blitzer et al (1998) reported their 13-year experience in 901 patients who underwent 6300 injections; adverse effects included "mild breathiness and coughing on fluids" in the adductor SD patients, and "mild stridor" in abductor SD patients. Adverse events may result from diffusion of drug from the target muscle to adjacent muscles, and adjusting the dose, distribution, and timing of injections may decrease the frequency of adverse events. To conclude, the Clinical Practice Guideline states" "Botulinum toxin is beneficial despite the potential need for repeated treatments considering the lack of other effective interventions for spasmodic dysphonia." Botulinum toxin injections into the muscles that are spasming have thus become the mainstay of therapy starting in the late 1980s. Voice therapy for treating spasmodic dysphonia is useful as an adjunct to botulinum toxin, but voice therapy alone for treating spasmodic dysphonia does not work for everyone and study results have not been consistent.
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References:

1. American Academy of Otolaryngology-Head and Neck Surgery, Clinical practice guideline: Hoarseness (Dysphonia). Otolaryngology–Head and Neck Surgery, Vol 141, No 3S2, September 2009. http://www.entnet.org/Practice/upload/Final-Hoarseness-Guideline.pdf
2. Blitzer A, Brin MF, Stewart CF. Botulinum toxin management of spasmodic dysphonia (laryngeal dystonia): a 12-year experience in more than 900 patients. Laryngoscope 1998; 108:1435– 41. http://www.ncbi.nlm.nih.gov/pubmed/9778279
3. Boutsen F, Cannito MP, Taylor M, et al. Botox treatment in adductor spasmodic dysphonia: a meta-analysis. J Speech Lang Hear Res 2002; 45:469–81. http://jslhr.asha.org/cgi/reprint/45/3/469
4. Cannito MP, Woodson GE, Murry T, et al. Perceptual analyses of spasmodic dysphonia before and after treatment. Arch Otolaryngol Head Neck Surg 2004; 130:1393–9. http://www.ncbi.nlm.nih.gov/pubmed/15611398
5. Courey MS, Garrett CG, Billante CR, et al. Outcomes assessment following treatment of spasmodic dysphonia with botulinum toxin. Ann Otol Rhinol Laryngol 2000; 109:819 –22. http://www.ncbi.nlm.nih.gov/pubmed/11007083
6. Stong BC, DelGaudio JM, Hapner ER, et al. Safety of simultaneous bilateral botulinum toxin injections for abductor spasmodic dysphonia. Arch Otolaryngol Head Neck Surg 2005; 131: 793–5. http://www.ncbi.nlm.nih.gov/pubmed/16172357
7. Sulica L. Contemporary management of spasmodic dysphonia. Curr Opin Otolaryngol Head Neck Surg 2004; 12:543– 8. http://www.ncbi.nlm.nih.gov/pubmed/15548915
8. Troung DD, Rontal M, Rolnick M, et al. Double-blind controlled study of botulinum toxin in adductor spasmodic dysphonia. Laryngoscope 1991; 101:630–4. http://onlinelibrary.wiley.com/doi/10.1288/00005537-199106000-00010/abstract
9. Watts C, Whurr R, Nye C. Botulinum toxin injections for the treatment of spasmodic dysphonia. Cochrane Database of Systematic Reviews 2004, Issue 3. http://www.ncbi.nlm.nih.gov/pubmed/15266530 *(conclusions unchanged as of 2009)*

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NHS Leeds