

**PATIALLY EXCLUDED POLICY – PE102
BOTULINUM TOXIN (BOTOX) TYPE A (DYSPORT) FOR THE MANAGEMENT OF
HYPER SALIVATION IN CHILDREN**

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1. Policy Summary

1.1 Botulinum toxin (Botox) type A (dysport) is produced naturally by the bacterium clostridium botulinum. When purified, it can be used in tiny, controlled doses to relax excessive muscle contraction¹. When injected into sublingual, parotid and submandibular glands, the botulinum toxin acts on the nerves around the salivary glands reducing the amount of saliva produced¹. This policy looks at botulinum toxin (Botox) type A (dysport) as a treatment and management of hypersalivation in a child under the age of 18. This procedure should not be commissioned. Funding requests are considered, if there are exceptional circumstances, by the Individual Funding Request (IFR) Panel. This partial exclusion policy offers some guidance to the referring clinician and the IFR Panel when considering such requests.

2. Background to the Procedures

2.1 Excessive drooling or dribbling, also known as sialorrhoea, hypersalivation or excessive salivation can be defined as salivary incontinence or the involuntary spillage of saliva over the lower lip². Excessive drooling is often a problem in children with cerebral palsy, intellectual disability or other neurological impairments. It can have implications for both the child and parents and excessive drooling can cause significant skin irritation and require frequent changes of clothes and/or bibs³.

2.2 As neurological control of the tongue and bulbar musculature develops, salivary “continence” normally occurs by 15–18 months. However, a high number of typically developing children will continue to drool up until the age of 3 years⁴.

2.3 Drooling beyond the age of 4 years is neurodevelopmentally abnormal. Chronic “sialorrhoea” is seen in children with abnormal oral sensation and/or motor control and more infrequently when there is excessive production of saliva and is considered pathological if present after 4 years⁴.

3. Rationale Behind Policy Decision

3.1 When considering the use of botulinum toxin (Botox) type A (dysport) in the treatment of hypersalivation in children, there is limited evidence on the clinical effectiveness and no evidence on the cost effectiveness of the treatment. There is further a lack of available information on the long term effects of performing the treatment (NHS UK Medicines Information, medicine question and answer sheets). However, it is clear that there is a specialist demand in various groups of patients for the use of this treatment and

implementation of a policy to reflect an appropriate level of guidance on administering botulinum toxin type A for hypersalivation in children is required.

4. Policy Procedure Guidance to CCG

4.1 The following guidance will be considered by the IFR panel when considering requests on an individual patient basis:

- a) What is the cause of the hypersalivation (e.g. neurodevelopmental delay, cerebral palsy⁵)?
- b) What is the severity of the hypersalivation and impact on ability to perform daily activities (e.g. attending school, regularity of changing clothing, ability to eat and drink)?
- c) Is there evidence of perioral sores and infections caused or made worse by the hypersalivation?
- d) What clinically appropriate treatments and interventions have been tried already (e.g. Hyoscine patches or Glycopyrolate⁶)
- e) Has any surgery been performed already (e.g. adenoidectomy, tonsillectomy or adenotonsillectomy)?
- f) Has the child been seen by a consultant paediatrician and is there support from such a consultant for the treatment?
- g) Have all options, including benefits and risks been explained to the child (if age appropriate) and the main carer?
- h) How is this child different from a cohort of children with a similar presentation?

5. References

1. Great Ormond Street Hospital for Children NHS Foundation Trust. *Salivary Gland Injections with Botulinum Toxin.*; 2014. <http://www.gosh.nhs.uk/medical-information-0/procedures-and-treatments/salivary-gland-injections-botulinum-toxin>.
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6. NICE: National Institute for Health and Care Excellence. Hypersalivation: oral glycopyrronium bromide. <https://www.nice.org.uk/advice/esuom15/chapter/intervention-and-alternatives>. Published 2013.