### HMMC Recommendation: Botulinum toxin type A (Botox®) is NOT RECOMMENDED for routine commissioning in the treatment of hypersalivation.

For patients with severe symptoms profoundly affecting quality of life and refractory to other systemic treatments, an individual funding request may be submitted. The application must include details of objective measures to be used to assess treatment response.

<table>
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<th>What it is</th>
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| Botulinum toxin type A (Botox®) | Neurotoxin complex blocking peripheral acetylcholine release at presynaptic cholinergic nerve terminals | Treatment of hypersalivation | September 2012 | Final | NICE – None
| | | | | SMC - None |

#### EFFICACY
- Small scale, unblinded studies support efficacy in reducing saliva production and improving quality of life in patients with severe drooling, unresponsive to other therapies.
- No long term data is available.

#### SAFETY
- Appears to be well tolerated.
- No long term safety data.

#### COST
- Annual cost to NHS Hertfordshire is estimated at £24k.

#### PATIENT FACTORS
- None.

**Assessment against Ethical Framework**

**Evidence of Clinical Effectiveness**
- Most clinical studies involved small numbers of patients. There was no blinding, randomisation or control group in most cases.
- No long term data on efficacy and safety is available.
- The doses used in trials varied, as did the route and method of administration (ultrasound guided versus not).
- The studies reviewed suggest that botulinum toxin is well tolerated, reduces saliva production and that where reported the benefit is meaningful to patients treated.

**Cost of treatment and Cost Effectiveness**
- The number of patients within NHS Hertfordshire eligible for treatment is unknown. The business case supplied to support the application estimates 10 patients across Hertfordshire will be eligible for treatment.
- The total treatment cost is approximately £2.4k/patient/year.
- There is no information on cost effectiveness.

**The needs of the population**
- Hypersalivation is a common symptom of many neurological diseases. The main agents used for treatment are anticholinergic medications, such as trihexyphenidyl, benztropine, atropine and hyoscine. These agents vary in their effectiveness and may not be well tolerated. Surgical intervention and local irradiation of salivary glands are other modes of treatment but are often considered unsuitable due to the invasiveness of the procedures. Motor or behavioural therapy, to improve the oral musculature, may also be appropriate in some cases.

**The needs of the community**
- If used more widely than is being suggested, this agent may create a cost pressure which could have an impact on the local health economy which already has to identify savings.

**Equity**
- Patients with significant neurological problems may have a reduced quality of life if they are unable to access this treatment, and may not be in a position to ask for treatment.

**Policy Drivers**
- 3 requests for this treatment have been made via IFR in the last 12 months.

**Implementability**
- No issues identified.

**References**