PR 2016-17: Botulinum toxin for sialorrhoea in adults

Recommendation

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national guidance, the baseline position (with respect to activity, costs and expenditure), other CCG policies, evidence relating to the burden of disease and the safety, clinical- and cost-effectiveness of treatment, and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account, the PRGC recommends that:

- Botulinum toxin is **funded for the treatment of uncontrolled sialorrhoea** in adults with motor neurone disease, Parkinson's disease and cerebral palsy where:
    - all other conservative and pharmacological therapies have failed or are contraindicated AND
    - sialorrhoea causes significant functional impairment or has a significant impact on the patient's quality of life
- Where treatment is effective, repeated injections should not be given more frequently than every 12 weeks; treatment should be discontinued where there is insufficient clinical benefit
- Botulinum toxin should be administered by a suitably trained individual and appropriate arrangements should be in place for clinical governance, consent and audit.

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*

Date: September 2016

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Kent and Medway Policy Recommendation and Guidance Committee
Policy Recommendation

Policy:	**PR 2016-17: Botulinum toxin for sialorrhoea in adults**
Issue date:	**August 2016**
Review date:	**August 2019**

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national guidance, the baseline position (with respect to activity, costs and expenditure), other CCG policies, evidence relating to the burden of disease and the safety, clinical- and cost-effectiveness of treatment, and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account, the PRGC recommends that:

- Botulinum toxin[1] is funded for the treatment of uncontrolled sialorrhoea in adults[2] with motor neurone disease, Parkinson's disease and cerebral palsy where:
    - all other conservative and pharmacological therapies have failed or are contraindicated AND
    - sialorrhoea causes significant functional impairment or has a significant impact on the patient's quality of life
- Where treatment is effective, repeated injections should not be given more frequently than every 12 weeks; treatment should be discontinued where there is insufficient clinical benefit
- Botulinum toxin should be administered by a suitably trained individual and appropriate arrangements should be in place for clinical governance, consent and audit

See overleaf for background information and supporting rationale.

This policy recommendation will be reviewed in light of new evidence or guidance from NICE.

Clinical Commissioning Groups in Kent and Medway will always consider appropriate individual funding requests (IFRs) through their IFR process.

Supporting documents

South East CSU Health Care Intervention Appraisal and Guidance (HCiAG) team (2016) *Botulinum toxin for the treatment of adults with sialorrhoea – Briefing note*

Equality Analysis Screening Tool – Botulinum toxin for sialorrhoea in adults (2016)

[1] Botulinum toxin is listed as a National Tariff Excluded Drug

[2] NHS England is responsible for commissioning all specialist neuroscience services for children

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Key points and rationale

What is sialorrhoea?
Sialorrhoea (excessive drooling, also known as ptyalis) occurs when there is excess saliva in the mouth beyond the lip line. Pathologic sialorrhoea can be an isolated phenomenon due to hypersalivation, or can occur in conjunction with several neurologic disorders such as motor neurone disease (MND), cerebral palsy (CP), Parkinson's disease (PD), or as a side effect of medications. Sialorrhoea may lead to clinical and functional complications, such as impairment in social functioning, aspiration, skin breakdown, bad odour, and infection.

What is it like to live with sialorrhoea?
One study (N=109) was identified which assessed the impact of sialorrhoea on quality of life (QoL) in people with Parkinson's disease compared to age matched controls using the PDQ-39 (validated) tool. There was no significant different in overall QoL between droolers and non-droolers, however droolers scored worse on the activities of daily living subscale of the PDQ-39.

What are the treatment options for sialorrhoea?
Conservative options include biofeedback and positioning techniques. Treatment options for sialorrhoea include pharmacological therapies (including antimuscarinic agents), radiation therapy, surgery involving the alteration of the anatomy of the salivary glands and botulinum toxin injections into the parotid and submandibular glands.

What is botulinum toxin?
Botulinum toxin (BTX) is a powerful neurotoxic agent synthesised by the anaerobic bacterium *Clostridium botulinum*. Different strains of *C. botulinum* produce seven immunologically distinct forms of botulinum neurotoxin, labelled BTX-A to BTX-G. Botulinum toxin is a National Tariff Excluded Drug. It is not licensed for the treatment of sialorrhoea.

What national guidance is available on the use of BTX to treat sialorrhoea?
- NICE Guideline (NG) 42 on MND (2016) recommends that if first line treatment for sialorrhoea is not effective, not tolerated or contraindicated, referral to a specialist service for BTX-A should be considered. Antimuscarinic medicine (or glycopyrrolate in people with MND who have cognitive impairment) is considered as the first-line treatment.
- NICE Clinical Guideline (CG) 35 on PD in people aged over 20 (2006) recommends people with Parkinson's disease should be "treated appropriately" for sialorrhoea; the full guideline lists a number of conservative and treatment options including injection of salivary glands with BTX-A.
- Draft NICE CG on CP in people aged under 25 (2016) recommends consideration of specialist assessment and use of BTX-A injections to the salivary glands with ultrasound guidance to reduce the severity and frequency of drooling if anticholinergic drugs provide insufficient benefit or are not tolerated. Conservative options should be part of saliva control management before initiating pharmacological treatment.

What is the evidence base?
A meta-analysis including 8 randomised controlled trials (RCTs) compared the effectiveness of BTX with placebo injections in patients with sialorrhoea (N=181). A significant improvement in drooling severity at 4 weeks was observed in BTX patients; 3 studies reported sustained improvement in drooling severity at 12 weeks post BTX treatment. The most common side effects reported in the meta-analysis were increased saliva thickness (3.9%), dysphagia (3.3%), xerostomia or dry mouth (3.3%), and pneumonia (2.2%). No cost effectiveness studies on the use of BTX for sialorrhoea in a UK setting were identified.

What is the baseline position in Kent and Medway?
None of the Kent and Medway CCGs currently has a policy on the use of BTX for the treatment of sialorrhoea. Correspondence with Trusts suggests that patients are being treated with BTX for sialorrhoea at Maidstone and Tunbridge Wells NHS Trust, Medway NHS Foundation Trust and East Kent Hospitals University NHS Foundation Trust. It is likely that where BTX is being used to treat sialorrhoea, Trusts are paying for the BTX and CCGs are paying for the associated activity.

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The estimated cost of one treatment with BTX given as an outpatient procedure is between £300 and £460; the estimated minimum cost of surgery for sialorrhoea is £700.

Why is BTX recommended for the treatment of sialorrhoea in Kent and Medway?
BTX is recommended by NICE as a treatment option for sialorrhoea for patients with motor neurone disease, Parkinson's disease and cerebral palsy.

Change sheet

Reason for review:
Currently there is no Kent and Medway policy on the use of BTX for the treatment of sialorrhoea. An individual funding request (IFR) has been received for the treatment for sialorrhoea with BTX; this was triaged out of the IFR process for policy development as additional cases could be envisaged.

Change from baseline:
Although Kent and Medway CCGs do not currently have a policy on the use of BTX for the treatment of sialorrhoea, correspondence with local Trusts indicates sialorrhoea patients are currently being treated with BTX. It is likely that where BTX is being used to treat sialorrhoea, Trusts are paying for the BTX (as it is a National Tariff Excluded Drug) and CCGs are paying for the associated activity. Implementation of this policy recommendation will mean CCGs will start to pay for the cost of BTX as well as the cost of the associated activity.

Estimated cost impact of implementing PR2016-17:
The estimated annual cost to Kent and Medway CCGs of funding BTX for sialorrhoea is £18,500–£47,800 (see Table 1). These estimates should be treated with caution as they use assumptions from a range of sources, several of which it has not been possible to verify; see accompanying briefing note for further information.

The cost impact of implementing this policy recommendation may be less than the estimates set out in Table 1 because it appears CCGs are already funding at least some of the activity relating to BTX administration; these offset costs have not been accounted for here as it has not been possible to accurately quantify them.

Table 1 – Estimated annual cost of funding BTX for sialorrhoea in Kent and Medway

CCG	Estimated number of sialorrhoea patients requiring BTX treatment	Estimated cost of implementing PR2016-17*
NHS Ashford CCG	3	£1,300 – £3,300
NHS Canterbury and Coastal CCG	5	£2,100 – £5,500
NHS Dartford, Gravesham and Swanley CCG	6	£2,600 – £6,800
NHS Medway CCG	6	£2,800 – £7,400
NHS South Kent Coast CCG	5	£2,100 – £5,500
NHS Swale CCG	2	£1,100 – £3,000
NHS Thanet CCG	3	£1,400 – £3,700
NHS West Kent CCG	11	£4,900 – £12,700
Total Kent and Medway	**40**	**£18,500 – £47,800**

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