Kent and Medway Policy Recommendation and Guidance Committee

PR 2016-11: Botulinum toxin for Frey's syndrome

Recommendation

- Botulinum toxin, and any associated activity, is **not routinely funded** for the treatment of Frey's syndrome
- Patients currently accessing botulinum toxin for the treatment of Frey's syndrome can continue to be able to do so whilst deemed appropriate by their clinician

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

Date: May 2016

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Kent and Medway Policy Recommendation and Guidance Committee

Policy Recommendation

Policy:	**PR 2016-11: Botulinum toxin for Frey's syndrome**
Issue date:	**May 2016**
Review date:	**May 2019**

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered 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], and any associated activity, is not routinely funded for the treatment of Frey's syndrome
- Patients currently accessing botulinum toxin for the treatment of Frey's syndrome can continue to be able to do so whilst deemed appropriate by their clinician

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 Frey's syndrome – Briefing note*

Equality Analysis Screening Tool – Botulinum toxin for Frey's syndrome (2016)

[1] Botulinum toxin is listed as a High Cost Drug Exclusion (Payment by Results Exclusion).

Key points and rationale

What is Frey's syndrome?

Frey's syndrome (FS) is the result of aberrant regeneration of cut postganglionic parasympathetic fibres between the otic ganglion and subcutaneous vessels when injury to the branches of the auriculotemporal nerve occurs. It may be a sequela of parotidectomy, submandibular gland surgery, radical neck dissection, infection or traumatic injury in the parotid region. Clinically, Frey's syndrome presents as increased sweating, flushing and warming over the preauricular and temporal areas after gustatory stimulus. This can occur for 3–6 months or for many years following surgery. There are no licensed pharmacological therapies for FS; however topical aluminium chloride hexahydrate is often used off-label.

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. For FS, BTX is administered by intracutaneous injection. It induces chemical denervation and paralysis of the muscles, effective both in striated muscle and eccrine glands. Botulinum toxin is a High Cost Drug excluded from Tariff.

What is the baseline position?

The Kent and Medway Health Economy National Tariff Excluded Drugs document for 2015/16 (also known as the High Cost Drug Manual [HCDM]) states that currently only the East Kent Federation of CCGs' commission BTX for the treatment of Frey's syndrome.

Kent and Medway CCGs do not routinely fund BTX-A for craniofacial hyperhidrosis.

What national and professional society guidance is available on the use of BTX to treat FS?

There is no NICE guidance relating to the treatment of FS. There is no UK, European or US professional society guidance for the treatment of FS.

What is the evidence base for the use of BTX to treat FS?

No studies assessing the impact of FS on quality of life were identified.

There are no randomised controlled trials published comparing the safety and efficacy of BTX injections to placebo or other treatments for FS.

Eight case series reporting on a total of 168 patients indicate BTX-A injections may lead to decreases in gustatory sweating (evaluated by the Minor's iodine starch test) and improvement in symptoms (measured by the Frey's Questionnaire Card; an unvalidated tool). The mean duration of effects ranged between 8 and 17 months. The benefit of BTX-A treatment on quality of life is unknown. BTX-A appears to be well tolerated; no serious or systemic adverse events were reported.

No cost effectiveness studies on the use of BTX for FS in a UK setting were identified.

Why is BTX not funded for the treatment of FS in Kent and Medway?

The impact of Frey's syndrome on quality of life is unclear. Furthermore, the evidence base relating to the clinical effectiveness and safety of BTX for the treatment of Frey's syndrome is poor, and the cost-effectiveness of BTX for FS in a UK setting has not been established.

Change sheet

Reason for review:

Current policies relating to patient access to BTX injections for Frey's syndrome differ across Kent and Medway; an area wide policy is required to ensure that all patients across the area are treated equitably.

Changes made to current policy:

The table below highlights the changes made to the existing policy on BTX for Frey's syndrome:

BOTULINUM TOXINS A and B: Indication(s): Frey's syndrome Commissioned By: East Kent Federation of CCGs	• Botulinum toxin, and any associated activity, is not routinely funded for the treatment of Frey's syndrome • Patients currently accessing botulinum toxin for the treatment of Frey's syndrome can continue to be able to do so whilst deemed appropriate by their clinician

Rationale for PR2016-11:

The impact of living with Frey's syndrome on quality of life is unclear. Furthermore, the evidence base relating to the clinical effectiveness and safety of BTX for the treatment of Frey's syndrome is poor, and the cost-effectiveness of BTX for FS in a UK setting has not been established.

Estimated cost impact of implementing this policy:

Only the East Kent Federation of CCGs (Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG) currently commission BTX for Frey's syndrome at an estimated cost of between £4,200 and £14,800 annually. However, because patients already accessing BTX for the treatment of FS can continue to be able to do so whilst deemed appropriate by their clinician, cost savings may not be realised in the short-term.

Implementation of this policy is likely to be cost neutral for other CCGs, however Medway CCG may also realise a small cost saving as, though current arrangements are unclear, it is possible they are funding some activity relating to BTX for FS.