Kent and Medway Policy Recommendation and Guidance Committee
PR 2016–10: Botulinum toxin for masseteric hypertrophy

Recommendation

The PRGC recommends that:

- Botulinum toxin[1], and any associated activity, is NOT routinely funded for the treatment of masseteric hypertrophy
- Patients already accessing botulinum toxin for the treatment of masseteric hypertrophy 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)*
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Kent and Medway Policy Recommendation and Guidance Committee

Policy Recommendation

Policy:	**PR 2016-10: Botulinum toxin for masseteric hypertrophy**
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 masseteric hypertrophy
- Patients already accessing botulinum toxin for the treatment of masseteric hypertrophy 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 masseteric hypertrophy – Briefing note*

Equality Analysis Screening Tool – Botulinum toxin for masseteric hypertrophy (2016)

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

Key points and rationale

What is masseteric hypertrophy (MH)?
Benign masseter muscle hypertrophy is a relatively rare clinical condition of uncertain aetiology. It is characterised by a soft swelling, near the angle of the mandible (can occur uni- or bilaterally), which can be associated with facial pain. In some cases, limitation of the mouth opening has been reported, particularly where muscles are focally dystonic with tension in the region of the hypertrophied muscle. Midline deviation as well as masseteric (hemi-masticatory) spasm has been reported in some cases. Masseteric hypertrophy can be prominent enough to be considered facially disfiguring.

Symptoms such as pain can be treated with muscle relaxants. Other treatments include bite adjustments or involve the use of splints on the teeth. Surgery has historically been the main mode of treatment for the cosmetic reduction of masseteric hypertrophy but injection of BTX-A into the muscle, which is generally considered to be a less invasive modality, has more recently been advocated.

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 MH, botulinum toxin is administered by intramuscular injection; it produces a selective paralysis and the subsequent atrophy of the masseter muscle. 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 masseteric hypertrophy.

What national and professional society guidance is available on the use of BTX to treat MH?
There is no NICE guidance relating to the treatment of MH. There is no UK, European or US professional society guidance for the treatment of MH.

What is the evidence base for the use of BTX to treat MH?
No studies assessing the impact of MH 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 MH.

Seven case series reporting on a total of 110 patients indicate treatment with BTX-A may reduce mean maximum bite force, the volume of masseter muscle, and the thickness of masseter muscle. Improvements were generally maintained for 3-4 months following treatment with BTX-A; follow up did not extend beyond 12 months. Patient oriented outcomes were not reported, therefore the benefit of BTX-A treatment on quality of life is unclear. BTX-A appears to be well tolerated; no serious or systemic adverse events were identified.

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

Why is BTX not funded for the treatment of MH in Kent and Medway?
The impact of masseteric hypertrophy on quality of life is unclear. Furthermore, the evidence base relating to the clinical effectiveness and safety of BTX for the treatment of muscle hypertrophy is poor, and the cost effectiveness of BTX for MH in a UK setting has not been established.

Change sheet

Reason for review:

Current policies relating to patient access to BTX injections for MH 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 masseteric hypertrophy:

<table>
<tr><th>Current Kent and Medway HCDM policy</th><th>New policy recommendation (PR2016-10)</th></tr>
<tr><td>BOTULINUM TOXINS A and B:
<table><tr><th>Indication(s):</th><th>Commissioned By:</th></tr><tr><td>Masseteric hypertrophy</td><td>East Kent Federation of CCGs</td></tr></table></td><td>Botulinum toxin, and any associated activity, is not routinely funded for the treatment of masseteric hypertrophy
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Rationale for PR2016-10:

The impact of living with masseteric hypertrophy on quality of life is unclear. Furthermore, the evidence base relating to the clinical effectiveness and safety of BTX for the treatment of masseteric hypertrophy is poor, and the cost effectiveness of BTX for MH 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 masseteric hypertrophy, at an estimated cost of ~£4,900 annually. However, because patients already accessing BTX for the treatment of MH 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 at MFT are unclear, it is possible they are funding some activity relating to BTX for MH.