East Kent Prescribing Group



Kent and Medway Policy Recommendation and Guidance Committee PR 2016- 09: Botulinum toxin for spasticity in adults

Recommendation

Botulinum toxin should be funded for spasticity in adult patients with:

- Focal or multifocal problems due to spasticity, and
- A dynamic spastic component as opposed to contracture, and
- Clearly identified goals for treatment and anticipated functional gains.

Approved by: East Kent Prescribing Group (Representing Ashford CCG, Canterbury and Coastal CCG,

South Kent Coast CCG and Thanet CCG)

Date: July 2016

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Kent and Medway Policy Recommendation and Guidance Committee Policy Recommendation

Policy:	PR 2016-09: Botulinum toxin for spasticity in adults	
Issue date:	May 2016	
Review date:	N/A – Static recommendation ¹	

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, 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 toxin² should be funded for spasticity in adult patients with:

- · Focal or multifocal problems due to spasticity, and
- A dynamic spastic component as opposed to contracture, and
- Clearly identified goals for treatment and anticipated functional gains

See overleaf for background information and supporting rationale.

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 spasticity in adults – Briefing note

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

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¹ This recommendation has been made static. It will only be reviewed if new information becomes available that is likely to have a material effect on the current recommendation.

² Botulinum toxin is listed as a High Cost Drug Exclusion (Payment by Results Exclusion).

Key points and rationale

What is spasticity?

Spasticity can be technically defined as 'velocity-dependent increased resistance to passive limb movement in people with upper motor neurone syndrome' and has a complex pathophysiology resulting in the loss of mobility and pain from spasms. Spasticity can be seen in both adults and children and is often associated with (but not limited to) the following conditions: stroke, multiple sclerosis, cerebral palsy and physical disability following traumatic brain injury. Treatments for spasticity include muscle stretching, splinting/ orthotics, botulinum toxin (BTX) and oral antispasmodic agents.

What is botulinum toxin?

Botulinum toxin 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 botulinum toxin type A (BTX-A) to type G (BTX-G). Three BTX-A products have marketing authorisation in the UK for the treatment of focal spasticity (Botox®, Dysport® and Xeomin®). For spasticity, BTX is administered by intramuscular injection. It induces chemical denervation and paralysis of the muscles with the effects lasting for 2-3 months. Botulinum toxin is a High Cost Drug excluded from Tariff.

What is the baseline position in Kent and Medway?

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 all Kent and Medway CCGs currently commission BTX for the treatment of spasticity. In addition, the East Kent Federation of CCGs commissions BTX for the treatment of "spasticity (including pain)". NHS England is responsible for commissioning BTX for children with focal spasticity.

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

BTX is recommended as an option for treating spasticity by NICE <u>Clinical Guideline (CG) 162:</u> <u>Stroke rehabilitation in adults</u> (2013), the Royal College of Physicians (RCP) <u>National guidelines on spasticity in adults: management using botulinum toxin</u> (2009), the RCP <u>National Clinical Guideline for Stroke</u> (2012), Scottish Intercollegiate Guidelines Network (SIGN) <u>Guidance 118: Management of patients with stroke</u> (2010) and SIGN <u>Guidance 130: Brain injury rehabilitation in adults</u> (2013). A NICE Technology Appraisal (TA) is planned for BTX for treating upper or lower limb focal spasticity associated with stroke however, this appraisal is not due to begin until January 2017.

Why are there local eligibility criteria for access to BTX for spasticity in adults?

The criteria included in the policy recommendation are consistent with those set out in the RCP National Guidelines *Spasticity in adults: management using botulinum toxin* (2009). This policy recommendation will be reconsidered when new guidance from the RCP is published (currently in progress but publication date uncertain).

Will implementation of this recommendation lead to a cost impact for Kent and Medway CCGs?

No. BTX for spasticity is currently commissioned across all Kent and Medway CCGs without formal eligibility criteria in place.

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Change sheet

Reason for review:

Current Kent and Medway CCGs' policies relating to BTX injections for spasticity differ across the region; 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 spasticity:

Current Kent and Medway HCDM policies		New policy recommendation (PR2016-09)
BOTULINUM TOXINS A & B:		Botulinum toxin should be funded for spasticity in
Indication(s):	Commissioned By:	adult patients with:Focal or multifocal problems due to spasticity, and
Spasticity	All CCGs	
Spasticity (inc. pain)	East Kent Federation of CCGs	A dynamic spastic component as opposed to contracture, and
		Clearly identified goals for treatment and anticipated functional gains

Rationale for changes to policy (as per table above):

- Current criteria are unclear; specifically the meaning of "spasticity (inc. pain)" has not been established.
- Brings local practice in line with Royal College of Physicians national guidelines (2009)

Estimated impact of change to policy on expenditure:

BTX for spasticity is currently commissioned across all Kent and Medway CCGs without formal eligibility criteria in place. Implementation of PR2016-09, which includes eligibility criteria, may therefore lead to a small decrease in activity.

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