Kent and Medway Policy Recommendation and Guidance Committee

PR 2014-09: Botulinum toxin type A for urinary incontinence due to neurogenic detrusor overactivity

Recommendation

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national guidance, evidence of clinical and cost-effectiveness, the baseline position and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommended that:

1) Botulinum toxin type A[1] is funded on the local NHS for the treatment of urinary incontinence due to neurogenic detrusor overactivity, provided the following criteria are met:
   a) anticholinergic agents and mirabegron have proved to be ineffective or poorly tolerated
   b) patient has urodynamically proven detrusor overactivity
   c) patient is willing and able to self-catheterise if needed.

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: October 2014
Address: c/o *Canterbury and Coastal CCG, Ground Floor, Council Offices, Military Road, Canterbury, Kent,CT1 1YW*
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Kent and Medway Policy Recommendation and Guidance Committee.

Policy Recommendation.

Policy:	**PR 2014-09: Botulinum toxin type A for urinary incontinence due to neurogenic detrusor overactivity**
Issue date:	**October 2014**
Review date:	**October 2017**
See PR 2014-10 for botulinum toxin type A for overactive bladder with symptoms of urinary incontinence, urgency and frequency	

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2) Botulinum toxin type A[1] is funded on the local NHS for the treatment of urinary incontinence due to neurogenic detrusor overactivity, provided the following criteria are met:
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This policy recommendation will be reviewed in light of new evidence or national guidance.

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

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

Supporting documents

- Health Care Intervention Appraisal and Guidance (HCiAG) team (2014) *Botulinum toxin for the treatment of overactive bladder (OAB) – Scoping report*

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Key findings and rationale

What is overactive bladder (OAB)?

Overactive bladder (OAB) is characterised by uncontrolled contraction of the bladder wall (detrusor muscle) producing urgency often with frequency and nocturia and sometimes leakage (urgency urinary incontinence). In many cases, the reason why an overactive bladder develops is not known. However, in some instances symptoms develop due to a neurological condition such as multiple sclerosis (MS) or after spinal cord injury (SCI).

While rarely life-threatening, incontinence may seriously influence the physical, psychological and social wellbeing of affected individuals.

What is the prevalence of neurogenic detrusor overactivity (NDO)?

According to estimates made by the manufacturer of Botox®, around 39 patients per 100,000 population would be eligible for treatment with botulinum toxin. This equates to around 663 patients across Kent and Medway, although not all of these patients would be willing to self-catheterise.

What is botulinum toxin type A?

Botulinum toxin is a powerful neurotoxic agent. When injected directly into the detrusor muscle it blocks the pre-synaptic release of acetyl choline, resulting in paralysis of the detrusor smooth muscle.

Botox® is currently the only botulinum preparation licensed for bladder dysfunctions. It is indicated for NDO with urinary incontinence due to subcervical SCI (traumatic or non-traumatic) or MS, not adequately managed with anticholinergics. The recommended dose for this indication is 200 Units; botulinum toxin units are not interchangeable from one product to another (see SPC). The cost of 200 Units of Botox® is £331.68 (with VAT); acute Trusts may receive a discount on the list price.

What does national guidance say?

According to NICE clinical guideline 148 (urinary incontinence in neurological disease; issued 2012), recommended treatment options include: behavioural management programmes, anticholinergic agents, botulinum toxin type A and augmentation cystoplasty. Mirabegron is recommended for patients in whom anticholinergic drugs are contraindicated or clinically ineffective or have unacceptable side effects (TA290).

What is the evidence base for botulinum toxin type A?

Botulinum toxin type A has been evaluated in two similarly designed short-term, phase 3, randomised, double-blind, placebo-controlled studies in patients with NDO due to SCI or MS inadequately controlled on anticholinergics (N = 468). Botulinum toxin type A 200 Units significantly reduced episodes of urinary incontinence per week versus placebo. At week 6, around 36–38% of botulinum toxin recipients and 8–10% of placebo recipients were fully continent. Botulinum toxin was also associated with statistically and clinically significant improvements in health-related quality of life compared to placebo (measured using the validated Incontinence Quality of Life [I-QOL] questionnaire).

The most common adverse events reported in both studies were urinary tract infection (49–56% for botulinum toxin type A 200U and 34–40% for placebo) and urinary retention (20% for

botulinum toxin type A 200U and around 3% for placebo). There are very limited data in patients aged over 65 years, while published results on repeated treatments are also limited.

NICE and the Scottish Medicines Consortium (SMC) both concluded that botulinum toxin was cost-effective compared to no treatment in people with neurogenic detrusor overactivity who are not adequately managed with anticholinergic medication.

What is the cost impact of implementing this policy recommendation?

The cost of prescribing Botox® for neurogenic detrusor overactivity to patients of Kent and Medway CCGs is estimated to be around £62,300 in year 1, £148,300 in year 2 and £254,100 in year 3. Current activity will offset these costs to a greater or lesser extent depending on the CCG. Displacement of drugs in some cases and the lower acquisition cost of Botox® (versus list price) may further offset the estimated cost impact.

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