Kent and Medway Policy Recommendation and Guidance Committee.
Policy Recommendation

Botulinum toxin type A for overactive bladder with symptoms of urinary incontinence, urgency and frequency - PR 2014-10

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 idiopathic overactive bladder, 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) multidisciplinary team review undertaken
   d) 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: Jan 2016
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Kent and Medway Policy Recommendation and Guidance Committee.
Policy Recommendation

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

Policy:	**PR 2014-10: Botulinum toxin type A for overactive bladder with symptoms of urinary incontinence, urgency and frequency**
Issue date:	**October 2014**
Review date:	**October 2017**

See PR 2014-09 for 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:

2) Botulinum toxin type A[1] is funded on the local NHS for the treatment of urinary incontinence due to idiopathic overactive bladder, 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) multidisciplinary team review undertaken
   d) patient is willing and able to self-catheterise if needed

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.

Exclusion).

Supporting documents

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

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.

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

What is the prevalence of OAB?
Using data on OAB prevalence provided in the NICE costing template for mirabegron (TA290), around 204 Kent and Medway patients would be eligible for treatment with botulinum toxin. Not all of these patients would be willing to self-catheterise. These estimates are consistent with those provided by the manufacturer of Botox® (around 13 patients per 100,000 population).

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 overactive bladder with symptoms of urinary incontinence, urgency and frequency, not adequately managed with anticholinergics. The recommended dose for this indication is 100 Units; botulinum toxin units are not interchangeable from one product to another (see SPC). The cost of 100 Units of Botox® is £165.84 (with VAT); acute Trusts may receive a discount on the list price.

What does national guidance say?
NICE has published clinical guidelines on the management of lower urinary tract symptoms in men (CG97) and urinary incontinence in women (CG171). Both recommend botulinum toxin as a treatment option in patients who have not responded to conservative management and anticholinergic agents. 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 idiopathic OAB inadequately controlled on anticholinergics (N = 1,105). Botulinum toxin type A 100 Units significantly reduced episodes of urinary incontinence per day versus placebo and recipients perceived a significant improvement in their condition. Botulinum toxin was also associated with statistically and clinically significant improvements in health-related quality of life compared to placebo (measured using the validated King's Health Questionnaire and Incontinence Quality of Life [I-QOL] questionnaire).

Urinary tract infections were more common in the botulinum toxin type A group versus the placebo group (~24% versus 9% across the entire treatment cycle). Other urologic events occurring more frequently in botulinum toxin type A recipients versus placebo recipients in both studies were dysuria, bacteriuria and urinary retention. There are very limited data in men, 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 idiopathic OAB inadequately managed with anticholinergic medication.

What is the cost impact of implementing this policy recommendation?
The cost of prescribing Botox® for OAB to patients of Kent and Medway CCGs is estimated to be around £93,600 in year 1, £148,800 in year 2 and £204,100 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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