South East London Area Prescribing Committee
Formulary recommendation

Reference	**020**
Intervention:	**Trospium (Flotros®) 20mg film coated tablets** (Trospium is an anticholinergic agent)
Date of Decision	**November 2014**
Date of Issue:	**December 2014**
Recommendation:	**AMBER - Specialist initiation, prescribing and supply for the first 6 months.**
Further Information	• Trospium is accepted for use in South East London for use in children aged 5 years and over with overactive bladder who respond to anticholinergics (oxybutynin, tolterodine or solifenacin) with regards to an improvement in their bladder symptoms but who suffer unacceptable central nervous system side effects. • These side effects are usually in the form of anxiety and other emotional, psychological, behavioural problems. Trospium does not cross the blood brain barrier and therefore is not associated with these CNS effects. • Initiation of trospium is restricted to consultant specialists in the Children's Bladder Clinic and the hospital will continue to prescribe and supply the drug for the first 6 months. • Trospium is not licensed for use in children aged < 12 years*. The specialist must explain this to parent/guardian and obtain informed consent. • Trospium tablets can be crushed and dispersed in water before administration but they may have a bitter taste • A pathway for the treatment of children with overactive bladder syndrome should be developed across South East London including all of the anticholinergic medicines used. The pathway should define the roles of the Children's Bladder Clinic and prescribers in primary care. The pathway should be submitted to the APC for consultation and approval within 6 months of the date of issue of this recommendation. * Trospium 20 mg tablets are licensed for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder (e.g. idiopathic or neurologic detrusor overactivity) from the age of 12 years and above.
Shared Care/ Transfer of care required:	Not required in view of the small patient number anticipated across the region. However, sufficient information will be communicated to the GP on a case by case basis to enable them to continue prescribing in those responding post 6 months.
Cost Impact for agreed patient group	From evidence evaluation and submission form: • The expected number of patients who will require trospium is 12-24 per annum across the total population served by the Trust (not just SEL). Using trospium instead of another anticholinergic is unlikely to affect resource utilisation in the Children's Bladder Clinic or in primary care.
Usage Monitoring & Impact Assessment	Acute Trusts: • Monitor usage on a 6-monthly basis and report back to APC. Audit to ensure use in line with local pathway.
	CCGs: • Monitor epact data

Evidence reviewed	References (from evidence evaluation)
	1. Scheife R et al Central nervous system safety of anticholinergic drugs for the treatment of overactive bladder in the elderly. Clinical Therapeutics, February 2005, vol./is. 27/2(144-153). 2. Doroshyenko O Clinical pharmacokinetics and pharmacodynamics of solifenacin. Clinical Pharmacokinetics, 2009, vol./is. 48/5(281-302). 3. Yoshida A. The forefront for novel therapeutic agents based on the pathophysiology of lower urinary tract dysfunction: Bladder selectivity based on in vivo drug-receptor binding characteristics of antimuscarinic agents for treatment of overactive bladder. Journal of Pharmacological Sciences, 2010, vol./is. 112/2(142-150). 4. BNF for Children 5. Lopez Pereira P. Trospium chloride for the treatment of detrusor instability in children. Journal of Urology, November 2003, vol./is. 170/5(1978-1981). 6. NEWT Guidelines for Admin of Medicines to patients with Enteral Feeding Tubes/Swallow Difficulties. Edition: 2nd edition 2010.

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.

b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS