South East London Area Prescribing Committee
Formulary recommendation

Reference	**006**
Intervention:	**Dutasteride 500mcg MR/Tamsulosin 400mcg (Combodart®) capsules for adult patients with moderate to severe symptoms of benign prostatic hyperplasia (BPH)** (Dutasteride – an inhibitor of type 1 and type 2, 5 alpha reductase isoenzymes (5-ARI) and Tamsulosin hydrochloride – an inhibitor of α_{1a} and α_{1d} adrenergic receptors in the stromal prostatic smooth muscle and bladder neck)
Date of Decision	**October 2013**
Date of Issue:	**November 2013**
Recommendation:	**Grey – not recommended**
Further Information	Whilst the benefits of combination therapy are clear as stated in NICE guidance, based on current evidence there appears to be little difference, or small marginal differences in efficacy between drugs of the same class and therefore the most cost effective treatment options should be used first line. Finasteride containing regimes are significantly less expensive than dutasteride containing regimes. If 1 patient is treated with Combodart® rather than tamsulosin and finasteride for one year, the increased cost of drug treatment is £161.44. The potential number of patients to be treated in the local community is high, and increasing with an aging population. Additionally, the published clinical trials did not provide enough robust evidence to allow a cohort of patients to be identified who would particularly benefit from Combadart® therapy. Based on current information it is suggested that treatment options for moderate to severe symptoms of BPH currently on joint formularies in South East London are sufficient to meet needs and are cost effective.
Shared Care/Transfer of care document required:	N/A
Cost Impact for agreed patient group	N/A Cost avoidance by using other therapies currently on the formulary. In South East London there are approximately 20,000 men with moderate to severe Lower Urinary Tract Symptoms (LUTS). Not all of these men have presented to their GP or a urology department for help with their LUTS. If 1000 patients from the local population with moderate to severe LUTS were treated with Combodart® rather than the current formulary agents (eg tamsulosin and finasteride), the additional cost would have been c£160k per annum.

Usage Monitoring & Impact Assessment	**Trusts** Ensure compliance with current formulary agents – both initiated prescriptions and recommendations from clinics.
	CCGs Epact data monitoring and exception reporting as needed of inappropriate use to Trust via medicines teams. **Clinical review of existing patients on Combodart® to consider a change to more cost effective therapies is recommended.**
Evidence reviewed	1. NICE Guidelines on the management of lower urinary tract symptoms in men. CG97. Accessed online via www.nice.org.uk on 26/9/13 2. Kristal et al. Race, ethnicity, obesity, health related behaviors and the risk of symptomatic benign prostatic hyperplasia. J Urol 2007; 177: 1395-1400 3. Summary of Product Characteristics – Combodart 0.5mg/0.4mg hard capsules. GlaxoSmithKline, last updated 30/05/2013. Accessed online via www.medicines.org.uk on 27/9/13. 4. NICE Clinical Knowledge Summaries (CKS), LUTS in men, age related (prostatism). Last updated August 2010. Accessed online via http://cks.nice.org.uk on 27/9/13 5. Lower urinary tract symptoms – Evidence update March 2012. A Summary of selected new evidence relevant to NICE clinical guideline 97. NHS Evidence Update 11. NHS evidence. Accessed online via www.evidence.nhs.uk on 27/9/13 6. European Association of Urology. Guidelines on the management of male lower urinary tract symptoms (LUTS), incl benign prostatic obstruction (BPO). 2012. Accessed online via http://www.uroweb.org/gls/pdf/12_Male_LUTS_LR%20May%209th%202012.pdf on 27/9/13 7. Nickel JC, Gilling P, Tammela TL et al. (2011) Comparison of dutasteride and finasteride for treating benign prostatic hyperplasia: the Enlarged Prostate International Comparator Study (EPICS). British Journal of Urology International 108: 388–94. 8. McConnell JD, Roehrborn CG, Bautista O, et al; Medical Therapy of Prostatic Symptoms (MTOPS) Research Group. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. N Engl J Med 2003 Dec;349(25):2387-98. 9. Roehrborn CG, Siami P, Barkin J, et al; CombAT Study Group. The effects of combination therapy with dutasteride and tamsulosin on clinical outcomes in men with symptomatic benign prostatic hyperplasia: 4-year results from the CombAT study. Eur Urol 2010 Jan;57(1):123-31. 10. NHS Regional Drug and Therapeutics Centre Drug Update. Fixed Dose Combinations (Part 1) – What is the evidence for their use? No 61, October 2008 11. Gupta AK, Arshad S, Poulter N; Antihypertensive agents compliance: compliance, safety and effectiveness of fixed dose combinations of anti-hypertensive agents. Hypertension 2010;55:399-407 12. Bangalore S, Kamalakkannan G, Parkar S, Messerli F H. Fixed-dose combinations improve medication compliance: a meta-analysis. American Journal of Medicine 2007; 120(8): 713-719 13. Summary of Product Characteristics – Finasteride 5mg film coated tablets. Pfizer, last updated 08/10/2012. Accessed online via www.medicines.org.uk on 30/9/13. 14. Walker A, Doyle S, Posnett J et al. Cost-effectiveness of single dose tamsulosin and dutasteride combination therapy compared with tamsulosin monotherapy in patients with benign prostatic hyperplasia in the UK. BJU International 2013 Sept, 112/5: 638-646

NOTES:

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

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