South East London Area Prescribing Committee
Formulary recommendation

Reference	**044**
Intervention:	**Duloxetine 20mg and 40mg capsules (Yentreve®) for the treatment of stress urinary incontinence in women** (Duloxetine is a combined serotonin (5-HT) and noradrenaline (NA) reuptake inhibitor)
Date of Decision	**December 2015**
Date of Issue:	**January 2016**
Recommendation:	**Amber – Initiation and first month's supply from urogynaecology specialist team**
Further Information	• Duloxetine 20mg and 40mg (Yentreve®) is supported for use in South East London within its licensed indication for the treatment of **moderate to severe** stress urinary incontinence (SUI) in women. • Duloxetine may be considered in line with the NICE clinical guideline on the management of moderate to severe stress urinary incontinence in women (2013): - Duloxetine is **not** a first-line treatment for women with predominant SUI. - First line treatment consists of lifestyle interventions, behavioural therapies and physical therapies (such as pelvic floor muscle training of at least 3 months' duration). - Whilst duloxetine should not be routinely offered as a second-line treatment for women with SUI, it may be offered as second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. - If duloxetine is prescribed, the initiating specialist should counsel women about its adverse effects to improve initial concordance. • Duloxetine will be trialled for an initial period of 3 months. The first month's supply will be provided by the initiating Trust and the GP will be requested to prescribe for a further 2 months. • Evidence suggests that duloxetine should be used in combination with pelvic floor muscle training to get maximum benefit. • Routine follow up will be carried out at 3 months by the specialist team to assess if use of duloxetine has been beneficial. Assessment will include the following outcome measures: - Reduction in Incontinence Episode Frequency (IEF) - Improvement in Incontinence Quality of Life (QoL-I) - Reduction in the use of incontinence pads (if applicable) and - Improvement in patient global impression of improvement scale (PGI-I) • Following this assessment the specialist will make a decision regarding continuing long term use of duloxetine and communicate this to the GP, along with information on the results of the outcome measures (outlined above). The results of these measures should be shared with the GP in order to provide baseline data for review of ongoing suitability. • In cases where continued prescribing is deemed clinically appropriate, this will be carried out in primary care by the GP. • Ongoing follow up by the specialist team will be managed on a case by case basis. However, the GP should review long-term treatment annually in primary care (or every 6 months for women over 75 years old).
Shared Care/ Transfer of care required:	No - however first month's supply to be provided by initiating Trust.

Cost Impact for agreed patient group	• It is estimated that 9-15 patients per month would be initiated on duloxetine (or up to 180 patients a year) in SEL. • Treatment is started at a lower dose of 20mg twice a day for the first 2 weeks and then increased to 40mg twice a day. The cost of the first 3 months treatment is £108.70 per patient. • If it is assumed that two-thirds of patients continue on long term therapy after the initial 3 month period, at a dose of 40mg twice a day, this would result in a total cost impact of up to ~£70,000 per year across SEL (including VAT). • There may be savings from reduced surgical procedures (such as tension free vaginal tape).
Usage Monitoring & Impact Assessment	Acute Trusts • Monitor and submit usage and audit data upon request to the APC.
	CCGs • Monitor EPACT data. • Exception reports from GPs if inappropriate transfer of prescribing to primary care is requested.
Evidence reviewed	**References (from evidence review):** 1. Hannested Y and Rortveit G et al. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trøndelag. J Clin Epidermol 2000 Nov;53(11):1150-7. 2. NICE Clinical Guideline 171 - Urinary incontinence in Women: Management 2013. accessed November 2015. 3. MHRA A summary of the evidence on the benefits and risks of vaginal mesh implants. October 2014. Accessed November 2015. 4. Summary of Product Characteristics – Yentreve 20mg and 40mg hard gastroresistant capsules. Eli Lilly &Company. Last revised 04/09/2015 5. SIGN 79 Management of urinary incontinence in primary care. December 2004 accessed November 2015 6. Dmochowski R et al. Duloxetine vs placebo in the treatment of North American women with stress urinary incontinence. J Urol 2003:170;1259-63 7. Millard R et al. Duloxetine vs placebo in the treatment of stress urinary Incontinence: a four-continent randomised clinical trial. BJUI Int 2004;93:311-318 8. Van Kerrebroek P et al. Duloxetine vs placebo in the treatment of European And Canadian women with stress urinary incontinence. BJG 2004;111:249-257 9. Ghoniem et al. Duloxetine compared to pelvic floor muscle training (PFMT) 2005. J Urol. 2005 May;173(5):1647-53 10. Cardozo L, Drutz HP et al. Duloxetine vs. placebo in women awaiting incontinence surgery. Obstet Gynaecol 2004 Sep; 104(3):511-9. 11. Bump R et al. Long-term efficacy of duloxetine in women with stress urinary incontinence. BJUI 2008;102:214-218 12. Paramananthan M , Ammar A , et al. Cochrane intervention review. Noradrenaline reuptake inhibitors (SNRI) for stress urinary incontinence in adults. Online Publication Date: July 2005. Assessed as up-to-date:MAR 2007 (abstract) accessed November 2015. 13. Das Gupta R, Caiado M, Bamber L. An evaluation of the cost-effectiveness of duloxetine as a treatment for women with moderate to-severe stress urinary incontinence. Journal of Medical Economics 2006;9:1–25. 14. Manning U. Gotsch, A. Minarzyk D et al. How are women with SUI-symptoms treated with duloxetine in real life practice? – Preliminary results from a large observational study in Germany international journal of clinical practice 2009 Dec: 63(12): 1724–1733 15.Martin C, Michel A, Anette Minarzyk A et al, Observational study on safety and tolerability of duloxetine in the treatment of female stress urinary incontinence in German routine practice Br J Clin Pharmacol. 2013 Apr; 75(4): 1098–1108.

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.