South East London Area Prescribing Committee
Formulary recommendation

Reference	**073**
Intervention:	**Conjugated oestrogens (0.45mg) and bazedoxifene acetate (20mg) combination preparation (Duavive® modified release tablets) for the treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus** (Duavive is a hormone replacement therapy)
Date of Decision:	**July 2017**
Date of Issue:	**August 2017**
Recommendation:	**Amber 2 - Initiation and minimum 3 month's supply from specialist gynaecology team/menopause clinic.**
Further Information:	• Patients with menopause should be managed in line with the NICE Pathway and NICE guideline on the diagnosis and management of menopause. • Duavive is a combination product containing conjugated oestrogens with bazedoxifene (0.45/20mg). It is licensed for the treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. • The SEL APC accepts Duavive (conjugated oestrogens with bazedoxifene 0.45/20mg) for use within its licence where **all** other progestin therapy is not appropriate. • Patients will have received at least 4 lines of treatment before Duavive is considered and will have been referred to the specialist menopause clinic. • Patients must have been considered for and, where appropriate, tried oral, transdermal and intrauterine forms of progestin therapy. Oral and transdermal therapy will be tried for a minimum of 3 months; intrauterine therapy will be tried for a minimum of 6 months. • Experience treating women older than 65 years with Duavive is limited and therefore not supported by this recommendation. • The European Public Assessment Report (EPAR) for Duavive states that because the number of women exposed, lack of data in older women, and duration of treatment, the available safety data do not allow for assessment of whether the incidence of rare but important adverse events (such as cardiovascular or cerebrovascular events, venous thromboembolism or cancer) is increased in women taking conjugated oestrogens and bazedoxifene compared with placebo, or historical data for conjugated oestrogens and medroxyprogesterone. • As with all other hormone replacement therapy, there should be a clear discussion with the patient regarding the risks and benefits of therapy to help them make an informed decision. • Treatment should be reviewed at 3 months to assess efficacy and tolerability. Review annually thereafter unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events). Refer to NICE CKS for further detail on reviewing patients.

Shared Care/ Transfer of care document	N/A
Cost Impact for agreed patient group	• It is estimated that around 70 patients will be appropriate for treatment with Duavive in SEL in line with the criteria outlined in the "Further Information" section. • This would result in a cost impact of around £14,000 (exc. VAT) across SEL. • This doesn't include offset savings from cost of discontinued HRT preparations or savings from reduced surveillance, biopsies and surgery.
Usage Monitoring & Impact Assessment	**Trusts** • Monitor use and submit usage data and audit reports (against this recommendation) upon request to the APC.
	CCGs • CCGs to monitor ePACT data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (extracted from evidence evaluation)** 1. Bazedoxifene for HRT. Drug and Therapeutics Bulletin April 2017 2. Menopause: diagnosis and management (NG23). National Institute for Health and Care Excellence. Available online here 3. Duavive tablets. Summary of Product Characteristics. Available online here (accessed 12/06/2017) 4. Oestrogen deficiency symptoms in postmenopausal women: conjugated oestrogens and bazedoxifene acetate. National Institute for health and Care Excellence Evidence Summary 3. Available online here (accessed 13/06/2017) 5. NICE Clinical Knowledge Summaries: Menopause. Available online at here (accessed 13/06/2017) 6. Duavive: Public Assessment Report October 2014. Available online here (accessed 12/06/2017) 7. Utian W, Yu H, Bobula J et al. Bazedoxifene/conjugated estrogens and quality of life in post-menopausal women. Maturitas 2009 **63** p329-335 8. Bachmann G, Bobula J, Mirkin S et al. Effects of bazedoxifene/conjugated estrogens on quality of life in postmenopausal women with signs of vulvar/vaginal atrophy. Climacteric 2010 13 p132-140 9. Pinkerton J, Harvey J, Lindsay R et al. Effects of bazedoxifene/conjugated estrogens on the endometrium and bone: a randomised trial. Journal of Clinical Endocrinology and Metabolism 2014 99(2) e189-e198 10. British National Formulary. Available online here (accessed 13/06/2017) 11. Oestrogens, conjugated, bazedoxifene acetate (Duavive), Jan 2017 SMC 1220/17 available online here (accessed 12/06/2017) 12. Conjugated oestrogens/bazedoxifene (Duavive®) All Wales Medicines Strategy Group 1511, May 2015. Available online here (accessed 12/06/2017) 13. Teitsson S, Bobula J, Haews C et al. Cost-effectiveness on conjugated estrogens/bazedoxifene for the treatment of vasomotor symptoms in the United States. Value Health 2015 **18** (7) A736

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