0.45 mg of conjugated oestrogens and bazedoxifene acetate equivalent to 20 mg bazedoxifene (Duavive®) modified release tablets for treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed not to fund the prescribing of conjugated oestrogens and bazedoxifene tablets 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.

There is a lack of evidence demonstrating increased efficacy to mitigate the increased cost of the product.
There are concerns about the adverse event profile of the product which introduces those of a new drug in addition to those already present due to the presence of oestrogen in the product.

This medicine is classified as BLACK for this indication

Summary of supporting evidence:

- The drug's manufacturer submitted data from 4 pivotal Phase 3 studies: studies 303, 305, 306, and 3307 to support the licensing application of bazedoxifene acetate 20mg/conjugated oestrogens 0.45 mg
- Study 303 demonstrated relatively low levels of endometrial hypoplasia after 24 months of treatment with bazedoxifene/conjugated oestrogens.
- Study 305 showed a reduction in number of hot flushes at week 4 with a further reduction at week 12 versus placebo for bazedoxifene/conjugated oestrogens
- Study 306 studies markers for vulvular/vaginal atrophy. It showed bazedoxifene/ conjugated oestrogens significantly ($P < 0.01$) increased superficial cells and decreased parabasal cells compared with placebo. Vaginal pH and 'most bothersome symptom' significantly improved with and improvements in vaginal dryness were also observed.
- Study 3307 evaluated biopsies in patients treated with bazedoxifene 20 mg / conjugated oestrogens 0.45 mg and bazedoxifene 20 mg / conjugated oestrogens 0.625 mg. Respectively, the incidence of endometrial hyperplasia / malignancy at month 12 was 0.32% (95% CI 0.01%; 1.76%) and 0.30% (2-sided 95% CI 0.01; 01.66%). The combined drugs also demonstrated significant increases in mean percent change from baseline in BMD of lumbar spine at Month 12 and Month 6 compared to placebo as well as well as in total hip BMD at Month 12.
    - In the clinical study programme, 3,322 women were exposed to conjugated oestrogens/ bazedoxifene for at least 1 year, and 1,999 women were exposed for 2 years

For details around the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/