South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference:	**137**
Intervention:	**Bijuve™ (estradiol 1mg and micronised progesterone 100mg) oral capsules - Hormone Replacement Therapies (HRT) for oestrogen deficiency symptoms in postmenopausal women** (Bijuve™ is a bioidentical hormone replacement therapy combination of estradiol and micronised progesterone)
Date of Decision:	**September 2022**
Date of Issue:	**October 2022**
Recommendation:	**GREEN – can be prescribed within agreed criteria for use in primary or secondary care**
Further Information:	· Bijuve™ (estradiol 1mg and micronised progesterone 100mg) oral capsules are approved for use in SEL in line with the licensed indication: continuous combined HRT for the management of oestrogen deficiency symptoms in women at least 1 year after last menses who have an intact uterus. · NICE guideline NG23 and NICE Clinical Knowledge Summaries – menopause recommend adopting an individualised approach to the management of menopause, based on the women's individual preferences, changing symptoms, concerns, past medical history and family history. · Bijuve™ is suitable as a first line oral continuous combined HRT option or an alternative if patients experience side effects from other HRT treatments. · Bijuve™ should be taken as a single daily oral capsule without interruption every evening with food. · In line with the current Summary of Product Characteristics (SmPC), continuous combined treatment may be started with Bijuve™ depending on the time since menopause and severity of symptoms: - Women experiencing a natural menopause should commence treatment with Bijuve™ 12 months after their last natural menstrual bleed. - For surgically induced menopause, Bijuve™ can be started immediately. - Patients changing from a continuous sequential or cyclical HRT preparation should complete the 28 day cycle and then switch to Bijuve™ · It should be noted the experience in treating women older than 65 years is limited for Bijuve™.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	· It is estimated there will be 40 – 60 patients across SEL eligible for Bijuve™ in this setting via the specialist menopause clinics. · This equates to a cost impact of approximately £6,400 per annum (£335 per 100,000 population) for SEL which is equivalent to the cost of Femiston Conti™; also a treatment option for patients in this setting. · Treatment would, however, be used as an alternative to current options, in particular to replace HRT regimens where separate estrogen and micronised progesterone are used, which is more expensive. Overall it would be expected the adding Bijuve™ to the already available HRT treatments in SEL would be cost-neutral.
Usage Monitoring & Impact Assessment	**Acute Trusts** · Monitor and submit usage and audit data on request to the SEL IMOC.
	SEL Borough Medicines Optimisation Teams: · Monitor primary care prescribing data. · Audit locally to ensure use in line with this recommendation. · Exception reports from GPs if inappropriate prescribing requests are made to primary care.

Evidence reviewed	References (from evidence evaluation)

1. Martin, K. and Barbieri, R., 2022. Treatment of menopausal symptoms with hormone therapy. Available here [Accessed 3 August 2022].
2. SPS - Specialist Pharmacy Service. 2020. Estradiol + progesterone. Available here at: [Accessed 24 August 2022].
3. Kuhl, H., 2005. Pharmacology of estrogens and progestogens: influence of different routes of administration. Climacteric, 8(sup1), pp.3-63. Available here [Accessed 3 August 2022]
4. Nice.org.uk. 2015. Overview | Menopause: diagnosis and management | Guidance | NICE. Available here [Accessed 3 August 2022].
5. Cks.nice.org.uk. 2022. Hormone replacement therapy (HRT) | Prescribing information | Menopause | CKS | NICE. [online] Available here [Accessed 24 August 2022].
6. Panay, N., 2019. Bioidentical HRT - British Menopause Society. [online] British Menopause Society. Available at here [Accessed 3 August 2022].
7. Medicines.org.uk. 2021. BIJUVE 1mg/100mg Capsules, soft - Summary of Product Characteristics (SmPC) - (emc). Available here [Accessed 3 August 2022].
8. Lobo RA, Archer DF, Kagan R, et al. A 17β-estradiol-progesterone oral capsule for vasomotor symptoms in postmenopausal women: a randomized controlled trial. Obstet Gynecol. 2018;132(1):161–170.
9. David F. Archer, Brian A. Bernick & Sebastian Mirkin (2019) A combined, bioidentical, oral, 17β-estradiol and progesterone capsule for the treatment of moderate to severe vasomotor symptoms due to menopause, Expert Review of Clinical Pharmacology, 12:8, 729-739
10. Nguyen, C., 2017. Center for drug evaluation and research application number: 210132Orig1s000. Accessdata.fda.gov. Available here [Accessed 10 August 2022].

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.

b) This SEL IMOC 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.