South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference:	**149**
Intervention:	**Ospemifene (Senshio™) for moderate to severe symptomatic vulvar and vaginal atrophy in post-menopausal women** (Ospemifene is a selective oestrogen receptor modulator [SERM])
Date of Decision:	**April 2024**
Date of Issue:	**April 2024 (time limited approval for 12 months)**
Recommendation:	**Amber 2 – specialist initiation and first prescription from the gynaecology specialist team. Review by gynaecology team at 3 months.**
Further Information:	• Ospemifene is accepted for use in South East London for the treatment of moderate to severe symptomatic vulvar and vaginal atrophy in post-menopausal women. • Ospemifene **is not a 1st line option** in this setting and is only approved where the following initiation criteria are met: (i) Symptoms of vulvar and vaginal atrophy adversely affect quality of life **AND** (ii) Topical lubricants have been adequately trialled and are not tolerated or ineffective or have been considered and are contraindicated **AND** (iii) At least two topical oestrogen preparations have been adequately trialled, and these have failed to control symptoms and improve quality of life or are not tolerated or have been considered and are contraindicated • As ospemifene should only be initiated for symptoms that adversely affect the quality of life (such as dyspareunia and vaginal dryness), a suitable tool to assess quality of life (such as the menopause-specific quality of life – MENQuaL) should be used before initiation and to assess improvements during ongoing treatment. • The initiation of ospemifene is restricted to gynaecology specialists, who will provide the first prescription. Treatment should be reviewed at 3 months by the initiating specialist to assess efficacy and tolerability. • Long term data on the use of ospemifene are lacking at time of the formulary decision. There should be regular review of patients to ensure ongoing effectiveness and safety. A careful appraisal of the risks and benefits should be undertaken **at least annually** (unless there are clinical indications for earlier review) taking into consideration other menopausal symptoms, effects on uterine and breast tissues, thromboembolic and cerebrovascular risks. Ospemifene should only be continued as long as the benefit outweighs the risk. • The dose of ospemifene is 60mg daily. • Further information can be found in the summary of product characteristics. • This approval is **time limited to one year** to enable experience of use with ospemifene. A report summarising patient numbers and outcomes with ospemifene over this period will be presented back to the Committee after 1 year, coordinated by the formulary applicant across all SEL Trusts. The report will include: – The total number of patients initiated by SEL Trusts on ospemifene – Whether use of ospemifene in line with this recommendation and the rationale for any deviation – Patient related outcomes, including: (i) Response to treatment (including, but not limited to, quality of life aspects) (ii) Adverse effects (iii) Number of patients switching from ospemifene to alternative treatments
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	• The applicant estimates there will be approximately 30 people in SEL per year eligible for treatment with ospemifene in this setting. • The cost of ospemifene is ~£515 per person per year. This equates to a cost impact of approximately £15,500 costs per year (< £1,000 per 100,000 population per year). After 5 years and beyond, there is not expected to be more than 100 patients on treatment in SEL at any one time, equating to ~£2,500 per 100,000 population.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor and audit usage of ospemifene as agreed and report back to the Committee in 12 months (data to be collated and presented no later than **April 2025**).
	SEL Borough Medicines Teams: • Monitor ePACT2 data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. Vaginal and vulval conditions | Treatment summaries | BNF | NICE. Available here [Accessed 06.03.24] 2. British Menopause Society: Consensus Statement – Urogenital atrophy. Available here: [Accessed 06 March 2024]. 3. Shionogi. Ospemifene (Senshio) 60 mg film-coated tablets. Summary of product characteristics. Electronic Medicines Compendium www.medicines.org.uk Last updated 19 March 2019. Available here: [Accessed 06 March 2024] 4. Overview | Menopause: diagnosis and management | Guidance | NICE. Available here: [Accessed 06 March 2024]. 5. Scottish Medicines Consortium: Ospemifene (Senshio) Medicines Advice. Available here: [Accessed 06 March 2024] 6. MHRA (2019) Hormone replacement therapy (HRT): further information on the known increased risk of breast cancer with HRT and its persistence after stopping. MHRA. Available here: [Accessed 06.03.24] 7. Collaborative Group on Hormonal Factors in Breast Cancer (2019) Type and timing of menopausal hormone therapy and breast cancer risk: individual participant meta-analysis of the worldwide epidemiological evidence. Lancet 394(10204), 1159-1168. [Accessed 06 March 2024]. 8. European Medicines Agency (EMA). European Public Assessment Report. Ospemifene (Senshio). EMEA/H/C/002780/0000. 20 November 2014. www.ema.europa.eu. Available here: [Accessed 06.03.24] 9. Simon JA, Ferenczy A, Black D, Castonguay A, Royer C, Marouf R, Beauchemin C. Efficacy, tolerability, and endometrial safety of ospemifene compared with current therapies for the treatment of vulvovaginal atrophy: a systematic literature review and network meta-analysis. Menopause. 2023 Aug 1;30(8):855-866. doi: 10.1097/GME.0000000000002211. Epub 2023 Jun 27. PMID: 37369079; PMCID: PMC10389189. [Accessed 06 March 2024] 10. Archer DF, Goldstein SR, Simon JA, Waldbaum AS, Sussman SA, Altomare C, et al. Efficacy and safety of ospemifene in postmenopausal women with moderate-to-severe vaginal dryness: a phase 3, randomized, double-blind, placebo-controlled, multicenter trial. Menopause. 2019;28:28 [Accessed 06 March 2024]. 11. Bachmann A. Ospemifene effectively treats vulvovaginal atrophy in postmenopausal women: results from a pivotal phase 3 study. Menopause: The Journal of The North American Menopause Society. 2010;Vol. 17:pp. 480/6 [Accessed 06 March 2024]. 12. Portman DJ, Bachmann GA, Simon JA, Ospemifene Study G. Ospemifene, a novel selective estrogen receptor modulator for treating dyspareunia associated with postmenopausal vulvar and vaginal atrophy. Menopause (New York, NY). 2013;20(6):623-30 13. Archer DF, Labrie F, Bouchard C, et al. Treatment of pain at sexual activity (dyspareunia) with intravaginal dehydroepiandrosterone (prasterone). Menopause 2015;22:950-963. doi: 10.1097/GME.00000 [Accessed 06 March 2024]. 14. Goldstein SR, Bachmann GA, Koninckx PR, et al. Ospemifene 12-month safety and efficacy in postmenopausal women with vulvar and vaginal atrophy. Climacteric 2014;17:173-182. doi: 10.3109/13697137.2013.83449 [Accessed 06 March 2024]. 15. Portman D, Palacios S, Nappi RE, Mueck AO. Ospemifene, a non-oestrogen selective oestrogen receptor modulator for the treatment of vaginal dryness associated with postmenopausal vulvar and vaginal atrophy: a randomised, placebo-controlled, phase III trial. Maturitas 2014;78:91-98. doi: 10.1016/ j.maturitas.2014.02.015 [Accessed 06 March 2024]. 16. Simon JA, Lin VH, Radovich C, Bachmann GA, Ospemifene Study Group. One-year long-term safety extension study of ospemifene for the treatment of vulvar and vaginal atrophy in postmenopausal women with a uterus. Menopause 2013;20:418-427. doi: 10.1097/gme.0b013e31826d36ba [Accessed 06 March 2024].

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.