South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation

Reference:	**125**
Intervention:	**Estradiol transdermal spray (Lenzetto®; 1.53 mg/spray) - Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women** [Estradiol is a form of the female hormone oestrogen]
Date of Decision:	**March 2021**
Date of Issue:	**April 2021**
Recommendation:	**GREEN – can be prescribed within agreed criteria for use in primary care**
Further Information	• Estradiol transdermal spray (Lenzetto®) is accepted as a treatment option for oestrogen deficiency symptoms in postmenopausal women in line with its licence*. • Lenzetto transdermal spray formulation may be a useful alternative transdermal treatment option in patients who are unable to comply with the instructions for use of other topical HRT products on the formulary (such as patches or gels) or experience adverse formulation reactions from other topical HRT preparations, such as local irritation. • Lenzetto is administered once daily, either as a monotherapy or as a continuous sequential treatment (when combined with a progestagen). • One metered-dose spray is administered once daily to the dry and healthy skin of the forearm as a starting dose. The dose may be increased to two metered-dose sprays daily to the forearm based on clinical response. • The maximum daily dose is 3 metered-dose sprays (4.59 mg/day) to the forearm. • Any dose increase should be based on the degree of menopausal symptoms and **should be made only after at least 4 weeks of continuous treatment**. • Dose increases should only be made on the advice of the clinician managing the patient's care. For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used. • When the degree of menopausal symptoms is not reduced after a dose increase, the patient should be back-titrated to the previous dose. • It should be noted that experience of treating women more than 65 years old is limited. • Patients should be re-evaluated periodically as clinically appropriate (e.g. 3-month to 6-month intervals) to determine if treatment is still necessary. A careful appraisal of the risks and benefits should be undertaken at least annually and HRT should only be continued as long as the benefit outweighs the risk. • The transdermal spray is to be used alone in women without a uterus, or in addition to a progestagen in women with an intact uterus. Only progestagens approved for addition to oestrogen treatment should be administered. • Further detail on Lenzetto, including how the spray should be administered, can be found in the summary of product characteristics and the patient information leaflet. * Lenzetto is licensed as HRT for oestrogen deficiency symptoms in postmenopausal women (in women at least 6 months since last menses or surgical menopause, with or without a uterus).

Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• The formulary applicant estimates that across SEL, approximately 100 women per year may switch from gel or patch to this new formulation. • The cost of Lenzetto spray is largely comparable (lower end of dosage range less costly than most other formulations) to the cost of most patch and gel formulations of topical HRT. • The difference in cost per annum between spray and gels are marginal. If using the highest dose of 3 sprays daily, increased costs between patches and spray may range between £4,500 (if switching from most costly patch e.g. Estradot or Femseven) and £8,500 (if switching from least costly Evorel patches; ~£500 per 100,000 population) per annum for SE London as a whole.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor usage and report back to SEL IMOC when requested.
	CCG Borough Medicines Optimisation Teams: • Monitor Epact 2 data
Evidence reviewed	**References (extracted from evidence evaluation):** 1. NICE Clinical Knowledge Summaries: Menopause. Available online at: https://cks.nice.org.uk/menopause (accessed 13/11/20) 2. NICE Guidelines: Menopause NG23 Full Guideline. Updated: 15/12/2019. Available online at: https://www.nice.org.uk/guidance/ng23 (accessed 13/11/20) 3. Summary of product characteristics. Lenzetto 1.53 mg/spray, transdermal spray, solution. Last revised 31/10/20. Available online at: https://www.medicines.org.uk/emc/product/11175/smpc#DOCREVISION 4. Buster et al. Low-Dose Estradiol Spray to Treat Vasomotor Symptoms. A Randomized Controlled Trial. Obstetrics & Gynaecology; 111(6), June 2008. 5. Fait et al. The use of estradiol metered-dose transdermal spray in clinical practice. Climacteric; 2018. 6. Kovács et al. Comparison of efficacy and local tolerability of estradiol metered-dose transdermal spray to estradiol patch in a network meta-analysis (2016). Climacteric, 19(5), pages 488-495. 7. British National Formulary. Accessed via: www.medicinescomplete.com. Last accessed 20/01/21.

NOTES:
a) SEL IMOC recommendations and minutes are available publicly via the Committee 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.**