

Serious Shortage Protocol (SSP) for Lenzetto® (estradiol) 1.53mg/dose transdermal spray – corresponding guidance on endorsement, prescription charges, remuneration and reimbursement plus Q&A.

SSP 027 for Lenzetto® (estradiol) 1.53mg/dose transdermal spray

There are three live SSPs for this product:

- SSP 026 – where the duration of treatment on the prescription exceeds 3 months and Lenzetto® is in stock.
- **SSP 027** – where the duration of treatment on the prescription is 3 months or less, Lenzetto® is not in stock, and substitution is deemed clinically appropriate **this SSP applies**.
- SSP 028 – Where the duration of treatment on the prescription exceeds 3 months, Lenzetto® is not in stock and substitution is deemed clinically appropriate.

1) Endorsement

The contractor must endorse the prescription form or Electronic Reimbursement Endorsement Message (EREM) as per Clause 9, Part II of the Drug Tariff.

Electronic prescription:

Where SSP endorsement functionality is available on the dispensing system the contractor must select SSP and input the three-digit reference number, leaving a space between SSP and the reference number, as shown below. The contractor must also select in the system the SSP item that has been supplied.

Example	Endorsement Option
<p>Prescription for Lenzetto® (estradiol) 1.53mg/dose transdermal spray x 56</p> <p>Pharmacy contractor supplies Evorel® 25 micrograms patches x 16 patches</p> <p>Pharmacy contractor selects in system Evorel® 25 micrograms patches x 16 patches</p>	<p>SSP 027</p>

Non-electronic prescription form:

Example	Endorsement
	Option
Prescription for Lenzetto® (estradiol) 1.53mg/dose transdermal spray x 56 Pharmacy contractor supplies Evorel® 25 micrograms patches x 16 patches	SSP 027 Pharmacy contractor endorses Evorel® 25 micrograms patches x 16 patches

2) Prescription charges

Where the quantity prescribed for Lenzetto® (estradiol) 1.53mg/dose transdermal spray is for **less** than three months, pharmacy contractors must take one prescription levy per item prescribed, where supply is in accordance with this SSP 027.

3) Remuneration

Supply in accordance with this SSP 027 will result in the following fees being paid to the contractor:

- One Single Activity Fee (£1.27)
- One SSP fee (£5.35)

4) Reimbursement

The supplied product in accordance with this SSP 027 will be reimbursed as if it was dispensed against a prescription. In this instance, contractors will be reimbursed the NHS list price for the quantity supplied and endorsed for the specified products and strengths listed below:

- Evorel® patches (25, 50 and 75 micrograms)
- FemSeven® patches (50 and 75 micrograms)
- Estraderm MX® patches (50 and 75 micrograms)
- Progynova TS® patches (50 micrograms)

The reimbursement price will account for VAT payment.

Q&A

Will the SSP apply to cross-border prescriptions?

Yes. Patients from England, Scotland, Wales or Northern Ireland who present their prescriptions for Lenzetto® (estradiol) 1.53mg/dose transdermal spray are eligible to receive a substituted product under the terms of this SSP 027.

Does the SSP apply to private prescriptions?

Yes. The scope of this SSP 027 applies to valid prescriptions that meets the requirements of the Human Medicine Regulations 2012, so it would cover both NHS and private prescriptions, unless where it stated otherwise on the SSP itself.

Will prescription charges apply under the SSP?

Yes, for prescriptions with a quantity less than three-months, patients who are not exempt from prescription charges would continue to pay for this as usual.

Can pharmacists use their professional judgement to supply an alternative product to patients?

Supply in accordance with this SSP 027 only allows supply of specific substitutions up to the duration of treatment prescribed. However, if the pharmacist thinks that an alternative product, other than those specified, would be suitable for the patient they should either contact the prescriber to discuss this (with the patient's consent) or direct the patient back to the prescriber.

How would the pharmacists determine the dosage of Lenzetto® and what should be supplied in accordance with this SSP?

Where the prescribed dosage of Lenzetto® is unclear, the pharmacist will need to discuss with the patient **and** use their professional judgment. When determining what should be supplied in accordance with this SSP 027, please refer to Annex A.

How would pharmacists determine a three-month supply?

Where it is not clear from the prescription what constitutes a three-month supply, the pharmacist will need to discuss with the patient **and** use their professional judgment.

What should pharmacists supply if the prescription states more than three months' supply should be dispensed?

If the prescription states that more than three months' supply is to be dispensed, the pharmacist should consider if supply in accordance with either of the following two SSPs would be appropriate:

- SSP 026 (where the duration of treatment on the prescription exceeds 3 months and Lenzetto® is in stock)
- SSP 028 (Where the duration of treatment on the prescription exceeds 3 months, Lenzetto® is not in stock and substitution is deemed clinically appropriate).

Can pharmacists supply more than three months' supply?

No, in accordance with this SSP 027, pharmacists will only be able to dispense the substituted product when the prescribed duration of treatment is three months' or less. Patients should be made aware that under the terms of this SSP 027, the prescription will be deemed complete, and no further supply can be made from the same prescription.

What can a pharmacist do if the patient does not consent to receiving the medicine supplied in accordance with this SSP?

Where a patient does not consent to receiving a substituted product in accordance with this SSP 027, the pharmacist should use their professional judgement to determine if other SSPs could be applicable.

Pharmacists in England must consider under their NHS terms of service if it is "reasonable and appropriate" to supply in accordance with this SSP 027 or another SSP, such as SSP 026 or SSP 028. If the pharmacist concludes that it is not reasonable or appropriate to supply the medication in accordance with any of the SSPs, the pharmacist must consider if they can dispense the prescription in the usual way 'in a reasonable timescale'. If they can, the ordinary obligation to dispense in accordance with the prescription applies. If they cannot, because the pharmacist has insufficient supply to fulfil the prescribed quantity within a reasonable timescale, the pharmacist may return the prescription, but if they do so, the pharmacist must provide the patient with appropriate advice about going back to the prescriber.

In the event that the pharmacist concludes that it is reasonable and appropriate to dispense in accordance with the SSP, but the patient persists in refusing to accept the option of a substituted product, the pharmacist may advise the patient that they will dispense in accordance with the SSP or not at all, if that is in accordance with their professional judgement.

The patient retains the right to either accept the professional decision of the pharmacist or to ask for their prescription to be returned to them.

Does the SSP apply to other Hormone Replacement Therapies?

No, this SSP 027 only applies to prescriptions for Lenzetto® (estradiol) 1.53mg/dose transdermal spray.

Is there any difference between the substituted products recommended?

Yes. Pharmacists should be mindful of the different dosing regimens of the substituted products specified under this SSP 027. For example, whether the patches are administered once or twice weekly.

Pharmacists should use their professional judgement to select the appropriate substitution on the basis of the brands available to them.

Does the SSP allow for estradiol brands not listed in Annex A to be substituted?

No, only the brands and strengths of estradiol patches listed within Annex A can be dispensed in accordance with this SSP 027.

Annex A - Dose conversion of estradiol (Lenzetto®) 1.53mg/dose transdermal spray to estradiol patches including the brands covered by this SSP

Current daily dosing regime of estradiol (Lenzetto®) 1.53mg/dose spray	Equivalent dose of estradiol patch	Patch options	Dosing	Quantity to supply	Availability
1 spray daily	25 microgram patch	Evorel®	Apply one patch TWICE WEEKLY	For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 16 x Evorel® patches	Can support a partial uplift in demand
2 sprays daily	50 microgram patch	Progynova TS®	Apply one patch WEEKLY	For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 4 Progynova TS® patches	Can support a partial uplift in demand
		FemSeven®	Apply one patch WEEKLY	For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 4 FemSeven® patches	Can support a partial uplift in demand
		Evorel®	Apply one patch TWICE WEEKLY	For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 8 Evorel® patches	Can support a partial uplift in demand

		Estraderm MX [®]	Apply one patch TWICE WEEKLY	For every 56 dose pack of Lenzetto [®] 1.53mg/dose transdermal spray supply 8 Estraderm MX [®] patches	Can support a partial uplift in demand
3 sprays	75 microgram patch	FemSeven [®]	Apply one patch WEEKLY	For every 56 dose pack of Lenzetto [®] 1.53mg/dose transdermal spray supply 3 Femseven [®] patches	Can support a partial uplift in demand
		Evorel [®]	Apply one patch TWICE WEEKLY	For every 56 dose pack of Lenzetto [®] 1.53mg/dose transdermal spray Supply 6 Evorel [®] patches	Can support a partial uplift in demand
		Estraderm MX [®]	Apply one patch TWICE WEEKLY	For every 56 dose pack of Lenzetto [®] 1.53mg/dose transdermal spray supply 6 Estraderm MX [®] patches	Can support a partial uplift in demand