

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

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</p> <p>Pharmacy contractor supplies Evorel® 25 micrograms patches x REDUCED QUANTITY IN LINE WITH SSP</p> <p>Pharmacy contractor selects in system Evorel® 25 micrograms patches x REDUCED QUANTITY IN LINE WITH SSP</p>	<p>SSP 028</p>

Non-electronic prescription form:

Example	Endorsement
	Option
Prescription for Lenzetto® (estradiol) 1.53mg/dose transdermal spray Pharmacy contractor supplies Evorel® 25 micrograms patches x REDUCED QUANTITY IN LINE WITH SSP	SSP 028 Pharmacy contractor endorses Evorel® 25 micrograms patches x REDUCED QUANTITY IN LINE WITH SSP

2) Prescription charges

For supply in accordance with this SSP 028, no prescription charges will be applicable for Lenzetto® (estradiol) 1.53mg/dose transdermal spray.

In order to ensure prescription charges are reconciled correctly, pharmacy contractors must endorse the correct SSP number.

3) Remuneration

Supply in accordance with this SSP 028 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 028 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 and a shorter duration of treatment under the terms of this SSP 028.

Does the SSP apply to private prescriptions?

Yes. The scope of this SSP 028 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?

As a supply in accordance with this SSP 028 is for a substituted product and a shorter duration compared to dispensing the prescription, for NHS prescriptions, no prescription charge will be applicable.

For patient's **EXEMPT** from prescription charges, the exemption should be marked in accordance with the usual procedure. When declaring prescription totals at the end of the month, pharmacists should continue to declare these prescriptions as exempt.

For patient's that **PAY** for their prescriptions, the pharmacist should mark on the prescription that a charge has been paid, however **NO** charge should be taken. When declaring prescription totals at the end of the month, pharmacists should declare these prescriptions as paid. The NHS Business Services Authority will amend total monthly figures to account for prescriptions covered by this SSP 028. In order for the NHS Business Services Authority to appropriately amend the total monthly figures that the prescription is correctly endorsed with the SSP number SSP 028.

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

Supply in accordance with this SSP only allows supply of specific substitutions and limited to a three-month quantity when the prescription is for a longer duration. 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 028, 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 less than three months' supply should be dispensed?

If the prescription states that either three months' supply or less is to be supplied to the patient, the pharmacist should consider if supply in accordance with SSP 027 is appropriate.

Can pharmacists supply more than three months' supply?

No, in accordance with this SSP 028, pharmacists will only be able to supply three months' supply of the substituted product. Patients should be made aware that under the terms of this SSP 028, the prescription will be deemed complete, and no further supply can be made from the same prescription above the three-month quantity.

If the pharmacy contractor is able to source supply of Lenzetto® the pharmacist should consider if supply in accordance with SSP 026 would be appropriate.

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 and a shorter duration of treatment in accordance with this SSP 028, the pharmacists 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 028 or another SSP, such as SSP 026 or SSP 027. 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 a substituted product and a shorter duration of treatment, 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 028 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 028. 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 028.

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 <u>TWICE WEEKLY</u>	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 <u>TWICE WEEKLY</u>	For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply	Can support a partial uplift in demand

				8 Evorel® patches	
		Estraderm MX®	Apply one patch <u>TWICE WEEKLY</u>	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 daily	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 <u>TWICE WEEKLY</u>	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 <u>TWICE WEEKLY</u>	For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 6 Estraderm MX® patches	Can support a partial uplift in demand