### Serious Shortage Protocol (SSP) for Ovestin® (estriol 0.1%) 1mg cream – corresponding guidance on endorsement, prescription charges, remuneration and reimbursement plus Q&A.

### SSP 024 for Ovestin® (estriol 0.1%) 1mg cream

There are three live SSPs for this product:

- SSP 020 where the duration of treatment on the prescription exceeds 3 months and Ovestin<sup>®</sup> is in stock.
- **SSP 024** where the duration of treatment on the prescription is 3 months or less, Ovestin<sup>®</sup> is not in stock, and substitution is deemed clinically appropriate **this SSP applies**.
- SSP 025 Where the duration of treatment on the prescription exceeds 3 months, Ovestin<sup>®</sup> 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
Prescription for Ovestin® (estriol	SSP 024
0.1%) 1mg cream x 15g	
Pharmacy contractor supplies Estriol 0.01% cream x 160g	
Pharmacy contractor selects in system Estriol 0.01% cream x 160g	

#### Non-electronic prescription form:

Example	Endorsement
	Option
Prescription for Ovestin® (estriol	SSP 024
0.1%) 1mg cream x 15g  Pharmacy contractor supplies Estriol 0.01% cream x 160g	Pharmacy contractor endorses Estriol 0.01% cream x 160g

#### 2) Prescription charges

Where the quantity prescribed for Ovestin® (estriol 0.1%) 1mg cream is for **less** than three months, pharmacy contractors must take <u>one</u> prescription levy, where supply is in accordance with this SSP 024.

#### 3) Remuneration

Supply in accordance with this SSP 024 will result in the following fees being paid to the contactor:

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

#### 4) Reimbursement

The supplied product in accordance with this SSP 024 will be reimbursed as if it was dispensed against a prescription. In this instance, contractors will be reimbursed the Part VIIIA reimbursement price for the quantity supplied for Estriol 0.01% cream.

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 Ovestin® (estriol 0.1%) 1mg cream are eligible to receive a substituted product under the terms of this SSP 024.

#### Does the SSP apply to private prescriptions?

Yes. The scope of this SSP 024 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 024 only allows supply of a specific substitution up to the duration of treatment prescribed. However, if the pharmacist thinks that an alternative product, 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 Ovestin® and what should be supplied in accordance with this SSP?

Where the prescribed dosage of Ovestin® 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 024, 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 020 (where the duration of treatment on the prescription exceeds 3 months and Ovestin® is in stock)
- SSP 025 (Where the duration of treatment on the prescription exceeds 3 months, Ovestin® is not in stock and substitution is deemed clinically appropriate).

#### Can pharmacists supply more than three months' supply?

No, in accordance with this SSP 024, 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 024, 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 024, 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 024 or another SSP, such as SSP 020 or SSP 025. 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 024 only applies to prescriptions for Ovestin® (estriol 0.1%) 1mg cream.

### Annex A - Dose conversion of estriol (Ovestin® 1mg) 0.1% cream to estriol 0.01% cream

	Ovestin® 1mg cream	Estriol 0.01% cream
Active ingredient	Estriol	Estriol
Strength	0.1% (1mg per 1g)	0.01% (100micrograms per 1g)
Applicator dose	1 applicator dose (0.5g of cream) = 0.5mg estriol	1 applicator dose (5g of cream) = 0.5mg estriol
Dose	1 application per day for the first weeks (maximally 4 weeks), followed by a gradual reduction, based on relief of symptoms, until a maintenance dosage (e.g., 1 application twice a week) is reached as directed.	1 application per day initially followed by a dose of 1 application twice a week for maintenance as directed after restoration of the vaginal mucosa has been achieved.