

# Serious Shortage Protocol (SSP) for Sandrena® (estradiol) 0.5mg and/or 1mg gel sachets – corresponding guidance on endorsement, prescription charges, remuneration and reimbursement plus Q&A.

## SSP 031 for Sandrena® (estradiol) 0.5mg and/or 1mg gel sachets

There are three live SSPs for this product:

- SSP 029 – where the duration of treatment on the prescription exceeds 3 months and Sandrena® is in stock.
- SSP 030 – where the duration of treatment on the prescription is 3 months or less, Sandrena® is not in stock, and substitution is deemed clinically appropriate.
- **SSP 031** – Where the duration of treatment on the prescription exceeds 3 months, Sandrena® 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><b>Example 1: Prescription for Sandrena® (estradiol) 0.5mg gel sachets</b></p> <p>Pharmacy contractor supplies Evorel® 25 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p> <p>Pharmacy contractor selects in system Evorel® 25 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>	<p>SSP 031</p>

<p><b>Example 2: Prescription for Sandrena® (estradiol) 1mg gel sachets</b></p> <p>Pharmacy contractor supplies Evorel® 50 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p> <p>Pharmacy contractor selects in system Evorel® 50 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>	<p>SSP 031</p>
<p><b>Example 3: Prescription for Sandrena® (estradiol) 0.5mg and 1mg gel sachets</b></p> <p>Pharmacy contractor supplies Evorel® 75 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p> <p>Pharmacy contractor selects in system Evorel® 75 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>	<p>SSP 031</p>

**Non-electronic prescription form:**

Example	Endorsement
<p><b>Example 1: Prescription for Sandrena® (estradiol) 0.5mg gel sachets</b></p> <p>Pharmacy contractor supplies Evorel® 25 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>	<p><b>Option</b></p> <p>SSP 031</p> <p>Pharmacy contractor endorses Evorel® 25 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>
<p><b>Example 2: Prescription for Sandrena® (estradiol) 1mg gel sachets</b></p> <p>Pharmacy contractor supplies Evorel® 50 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>	<p>SSP 031</p> <p>Pharmacy contractor endorses Evorel® 50 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>

<p><b>Prescription for Sandrena® (estradiol) 0.5mg and 1mg gel sachets</b></p> <p>Pharmacy contractor supplies Evorel® 75 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>	<p>SSP 031</p> <p>Pharmacy contractor endorses Evorel® 75 micrograms patches x <b>REDUCED QUANTITY IN LINE WITH SSP</b></p>
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## 2) Prescription charges

For supply in accordance with this SSP 031, no prescription charges will be applicable for Sandrena® (estradiol) 0.5mg and/or 1mg gel sachets.

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 031 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 031 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 Sandrena® (estradiol) 0.5mg and/or 1mg gel sachets are eligible to receive a substituted product and a shorter duration of treatment under the terms of this SSP 031.

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

Yes. The scope of this SSP 031 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 031 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 031. 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 031.

### **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 Sandrena® and what should be supplied in accordance with this SSP?**

Where the prescribed dosage of Sandrena® 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 031, 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 030 is appropriate.

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

No, in accordance with this SSP 031, 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 031, 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 Sandrena® the pharmacist should consider if supply in accordance with SSP 029 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 031, 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 031 or another SSP, such as SSP 029 or SSP 030. 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 031 only applies to prescriptions for Sandrena® (estradiol) 0.5mg and/or 1mg gel sachets.

**What if one of the two products under this SSP is available and the other is not?**

Where the pharmacy contractor is able to source one of the products under this SSP 031 but not the other, there are a number of options available to the pharmacist to ensure that the patient receives the equivalent dose. They could dispense, the prescribed item they have in stock and supply in accordance with the SSP for the other item. Alternatively, if the patient wants the same formulation, they could supply both items in accordance with the SSP (i.e. estradiol 75mcg patches).

For example, where a patient is prescribed both strengths of Sandrena® daily, the pharmacist can dispense Sandrena® 0.5mg gel sachets and estradiol 50microgram patches, if this approach is deemed appropriate. As a result, the pharmacy contractor would endorse SSP 031 only against the Sandrena® 1mg gel sachets which are being substituted in this example (please see Annex B for further details).

**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 031. 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 031.

**Annex A - Dose conversion of estradiol (Sandrena®) 500microgram and 1mg gel sachets to estradiol patches including the brands covered by this SSP**

Current daily dosing regime of estradiol (Sandrena®) gel	Equivalent dose of estradiol patch	Patch options	Dosing	Quantity to supply	Availability
<p><b>500microgram estradiol daily</b> <b>(1 x 500microgram sachet daily)</b></p>	<p><b>25 microgram patch</b></p>	<p>Evorel®</p>	<p>Apply one patch <b><u>TWICE WEEKLY</u></b></p>	<p>For every 7 x 500microgram gel sachets</p> <p>Supply</p> <p>2 Evorel® patches</p>	<p>Can support a partial uplift in demand</p>
<p><b>1mg estradiol daily</b> <b>(2 x 500microgram sachets</b> <b>OR</b> <b>1 x 1mg sachet)</b></p>	<p><b>50 microgram patch</b></p>	<p>Progynova TS®</p>	<p>Apply one patch WEEKLY</p>	<p>For every 14 x 500microgram gel sachets where only 500microgram gel sachets are prescribed</p> <p>OR</p> <p>For every 7 x 1mg sachets where only 1mg gel sachets are prescribed</p> <p>Supply</p> <p>1 Progynova TS® patch</p>	<p>Can support a partial uplift in demand</p>
		<p>FemSeven®</p>	<p>Apply one patch WEEKLY</p>	<p>For every 14 x 500microgram gel sachets where only 500microgram gel sachets are prescribed</p> <p>OR</p> <p>For every 7 x 1mg sachets where only 1mg gel sachets are prescribed</p>	<p>Can support a partial uplift in demand</p>

				<p>Supply</p> <p>1 FemSeven® patch</p>	
		Evorel®	<p>Apply one patch <b><u>TWICE WEEKLY</u></b></p>	<p>For every 14 x 500microgram gel sachets where only 500microgram gel sachets are prescribed</p> <p>OR</p> <p>For every 7 x 1mg sachets where only 1mg gel sachets are prescribed</p> <p>Supply</p> <p>2 Evorel® patches</p>	<p>Can support a partial uplift in demand</p>
		Estraderm MX®	<p>Apply one patch <b><u>TWICE WEEKLY</u></b></p>	<p>For every 14 x 500microgram gel sachets where only 500microgram gel sachets are prescribed</p> <p>OR</p> <p>For every 7 x 1mg sachets where only 1mg gel sachets are prescribed</p> <p>Supply</p> <p>2 Estraderm MX® patches</p>	<p>Can support a partial uplift in demand</p>
<p><b>1.5mg estradiol daily</b> <b>(3 x 500microgram sachets)</b></p>	<p><b>75 microgram patch</b></p>	FemSeven®	<p>Apply one patch WEEKLY</p>	<p>For every 21 x 500microgram gel sachets where only 500microgram gel sachets are prescribed</p> <p>OR</p>	<p>Can support a partial uplift in demand</p>



<p><b>OR</b></p> <p><b>1 x 1mg sachet and 1 x 500microgram sachet)</b></p>				<p>For every 7 x 1mg sachets AND 7 x 500microgram sachet where both 500microgram and 1mg gel sachets are prescribed</p> <p>Supply</p> <p>1 Femseven® patch</p>	
		Evorel®	<p>Apply one patch <b><u>TWICE WEEKLY</u></b></p>	<p>For every 21 x 500microgram gel sachets where only 500microgram gel sachets are prescribed</p> <p>OR</p> <p>For every 7 x 1mg sachets AND 7 x 500microgram sachet where both 500microgram and 1mg gel sachets are prescribed</p> <p>Supply</p> <p>2 Evorel® patches</p>	<p>Can support a partial uplift in demand</p>
		Estraderm MX®	<p>Apply one patch <b><u>TWICE WEEKLY</u></b></p>	<p>For every 21 x 500microgram gel sachets where only 500microgram gel sachets are prescribed</p> <p>OR</p> <p>For every 7 x 1mg sachets AND 7 x 500microgram sachet where both 500microgram and 1mg gel sachets are prescribed</p>	<p>Can support a partial uplift in demand</p>

				Supply 2 Estraderm MX <sup>®</sup> patches	
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**Annex B Endorsement Examples** *please note these examples are illustrative and use a one-month duration of treatment as an example.*

Current daily dosing regime of Sandrena® (estradiol) gel	Equivalent dose of estradiol patch	Patch options	Dosing of Substitution	Endorsement Examples		Other Info
				EPS	Paper	
0.5mg estradiol daily Example: 6 month supply = 168 0.5mg sachets	25 microgram patch	Evorel®	Apply one patch TWICE WEEKLY  Example: 3 month Supply = 24 patches	SSP 031	SSP 031 Evorel® 25 patch x 24	
1mg estradiol daily Example: 6 month supply = 168 1mg sachets	50 microgram patch	Progynova TS®  or FemSeven®	Apply one patch WEEKLY  Example: 3 month Supply = 12 patches	SSP 031	SSP 031 FemSeven® 50 patch x 12	
		Evorel®  or Estraderm MX®	Apply one patch TWICE WEEKLY  Example: 3 month Supply = 24 patches	SSP 031	SSP 031 Evorel® 50 patch x 24	

<p>1.5mg estradiol daily</p> <p>Example: 6 month supply = 168 0.5mg sachets &amp; 168 1mg sachets</p>	<p>75 microgram patch</p>	<p>Femseven®</p>	<p>Apply one patch WEEKLY</p> <p>Example: 3 month Supply = 12 patches</p>	<p>SSP 031</p> <p>ND</p>	<p>SSP 031 FemSeven® 75 patch x 12</p> <p>ND</p>	<p>When two strengths prescribed and covered by one substituted product, one must be endorsed with the SSP and patch provided and the other marked as 'Not Dispensed'</p>
		<p>Evorel®</p> <p>Or</p> <p>Estraderm MX®</p>	<p>Apply one patch TWICE WEEKLY</p> <p>Example: 3 month Supply = 24 patches</p>	<p>SSP 031</p> <p>ND</p>	<p>SSP 031 Evorel® 75 patch x 24</p> <p>ND</p>	<p>When two strengths prescribed and covered by one substituted product, one must be endorsed with the SSP and patch provided and the other marked as 'Not Dispensed'</p>

**Further Endorsement Examples** *please note these examples are illustrative and use a one-month duration of treatment as an example.*

Current daily dosing regime of Sandrena® gel (estradiol)	Equivalent dose	Options	Dosing of Substitution	Endorsement Examples		Other Info
				EPS	Paper	
1.5mg estradiol daily  Example: 6 month supply = 168 0.5mg sachets & 168 1mg sachets  <b>When 1 strength is available and another unavailable i.e. 0.5mg sachet available and 1mg unavailable</b>	50 microgram patch  <b>&amp; 0.5mg sachet daily</b>	Prodynova TS®  or FemSeven®	Apply one patch WEEKLY  Example: 3 month Supply = 12 patches	SSP 031  <b>Sandrena® 0.5mg gel sachet x 168</b>	SSP 031 FemSeven® 50 patch x 12  <b>Sandrena® 0.5mg gel sachet x 168</b>	
		Evorel®  Or Estraderm MX®	Apply one patch TWICE WEEKLY  Example: 3 month Supply = 24 patches	SSP 031  <b>Sandrena® 0.5mg gel sachet x 168</b>	SSP 031 Evorel® 50 patch x 24  <b>Sandrena® 0.5mg gel sachet x 168</b>	
1.5mg estradiol daily  Example: 6 month supply = 168 0.5mg sachets & 168 1mg sachets  <b>When 1 strength is available and another unavailable</b>	25 microgram patch  <b>&amp; 1mg sachet daily</b>	Evorel®	Apply one patch TWICE WEEKLY  Example: 3 month Supply = 24 patches	SSP 031  <b>Sandrena® 1mg gel sachet x 168</b>	SSP 031 Evorel® 25 patch x 24  <b>Sandrena® 1mg gel sachet x 168</b>	

i.e. 0.5mg sachet unavailable and 1mg available						
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