Department of Health & Social Care

NHS

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP 030

- SSP 029 – Where the duration of treatment on the prescription is for more than 3 months of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets and supplies of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets are available.
- SSP 030 **(this SSP)** – Where the duration of treatment on the prescription is for 3 months or less of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets, supplies of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets are unavailable, and substitution is deemed clinically appropriate.
- SSP 031 – Where the duration of treatment on the prescription is for more than 3 months of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets, supplies of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets are unavailable, and substitution is deemed clinically appropriate.

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Estradiol (Sandrena®) 500microgram and/or 1mg gel sachets **where the prescription is for 3 months or less of supply and supplies of either or both strengths are unavailable to fulfil the daily dose.** Where the prescription is for more than 3 months and supplies are unavailable, please refer to SSP 031. Where the prescription is for more than 3 months and supplies are available, please refer to SSP 029. **Pharmacists must ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP within 24 hours**

Legal category	POM

1. **Details of medication to be supplied under this SSP**

Name of medicine (including formulation and strength) to be supplied	Estradiol patch – the strength of estradiol patch is to be determined by the patients current daily dosing regime of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets as set out in **Annex A**. Due to the nature of the substitution, an exact replication of the duration of treatment may not be possible. Supply must be made to the nearest patch. Pharmacists must use the equivalence quantities as set out in **Annex A**, where the various brands of estradiol patches are listed with the different dosing instructions.
Quantity of this formulation (if applicable)	Total quantity supplied under this protocol should be a reasonable estimate of the prescribed duration of treatment in line with Annex A, where an exact equivalent dose is not possible due to the nature of the substitution. Dependent on the patient's current daily dose of estradiol (Sandrena®) 500microgram and/or 1mg gel sachets, supply to the nearest quantity of estradiol patches according to **Annex A**.
Substitution results in a change to whether the use is licenced	No

Scope for which this Serious Shortage Protocol (SSP) applies

The SSP applies to the following parts of the UK	UK-Wide

Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	All brand and generically prescribed NHS and private prescriptions.

Criteria for inclusion	• The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for estradiol (Sandrena®) 500microgram and/or 1mg gel sachets • The patient/carer consents to receiving the medicine supplied under this SSP. • All patients aged 18 years of age or above.
Criteria for exclusion	• The patient presents with a prescription for a medicine other than estradiol (Sandrena®) 500microgram and/or 1mg gel sachets • The patient presents a prescription which is not valid. • The patient/carer does not consent to receiving the medicine(s) supplied under this SSP. • Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive alternative medicine under this SSP. • Known previous hypersensitivity or severe adverse reaction to estradiol patches or their excipients. See counselling below. • Known previous lack of efficacy to estradiol patches. See counselling below. • Patients aged less than 18 years. • If the prescription for estradiol (Sandrena®) 500microgram and/or 1mg gel sachets received is for longer than 3 months, refer to SSP 029 where supplies are available or SSP 031 where supplies are not available.
Cautions including any relevant action to be taken	• Ensure that patients considered unsuitable for inclusion of SSP 029, 030 or 031 are promptly referred to their prescriber for review. • Using the prescription, clarify with patients their current daily dose of estradiol (Sandrena®) gel to inform the decision to switch to the appropriate strength of estradiol patch (see **Annex A** for dose equivalence of Sandrena® gel to estradiol patches and current availability). • Take into consideration the estradiol (Sandrena®) gel total daily dose and whether a patient has been prescribed the 1mg and/or 500microgram gel sachets. • Assure patients of the following: o the product they are being supplied in accordance with this SSP contains the same ingredient (estradiol) as Sandrena® gel. o although the dosing schedule and formulation (gel to patch) is different, they will receive a

	near equivalent daily dose of estradiol that should manage their symptoms. ○ clinical experts in menopause have been consulted in the production of this SSP and have advised on this approach. • Ensure that patients who are supplied in accordance with this SSP are counselled by the pharmacist with regards to monitoring and managing potential side effects, such as: ○ Vaginal 'breakthrough bleeding' ○ Skin irritation due to patch ○ Patches coming off or not adhering properly ○ Further information can be found here (NICE guidance) • Patients who experience persistent side effects from patches supplied in accordance with this SSP should be promptly referred back to their prescriber. • Patients with an intact uterus should be advised that they should continue to take the progestogen component of their HRT regimen, even after switching to estradiol patches. • If patients have reported a history of local irritation to patches and can confidently identify the patch they used, then pharmacists should: ○ Assess whether the reaction to the first brand was severe or not by considering if there were any widespread skin reactions or systemic side effects such as shortness of breath, flushing of the face, etc. ○ If the previous skin reaction was mild and local, seek consent from the patient to try another brand of patch, if available. ○ If the patient agrees to try an alternative brand of estradiol patches, advise them to remove the patch immediately if a problem occurs and see their GP. ○ If the previous reaction to patches was severe or the patient cannot identify which patch was tried previously, refer the patient to their prescriber. • The dose equivalents in **Annex A** are subject to individual variations in absorption and metabolism. Patients who feel their symptom control has been affected by the switch after 8 weeks should be referred back to their prescriber. • Ensure that the patient's prescriber and/or GP practice is notified of the current dose of estradiol (Sandrena®)

	gel as reported by the patient, and the strength and brand of estradiol patch supplied when supplying a patient in accordance with this SSP.
Special considerations for specific populations of patients	Particular care and caution should be taken to provide advice to patients who are considered at higher risk of experiencing the **nocebo** effect. Patients should be reassured as to the appropriateness and effectiveness of this alternative treatment as per the counselling points above. If there are significant concerns, refer the patient back to their prescriber for further advice.
Action to be taken if the patient is excluded	If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.
Action to be taken if the patient or carer declines the supply	If a patient/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.

Valid from:	19/05/2022
Expiry date:	19/08/2022
Reference number:	SSP 030
Version number:	1.0

Any queries regarding the content of this SSP which was issued by the Secretary of State for Health and Social Care, should be addressed to NHS Prescription Services.

You can get in contact by:
Email: nhsbsa.prescriptionservices@nhsbsa.nhs.uk
Telephone: 0300 330 1349
Textphone: 18001 0300 330 1349

You can also write to us at:

Newcastle	Middlebrook	Wakefield
NHS Prescription Services Bridge House 152 Pilgrim Street Newcastle upon Tyne NE1 6SN	NHS Prescription Services Ridgway House Northgate Close Middlebrook Horwich Bolton BL6 6PQ	NHS Prescription Services 4th Floor Wakefield House Borough Road Wakefield WF1 3UB

Change history

Version number	Change details	Date

2. Conditions under which this Serious Shortage Protocol (SSP) will operate

- The decision to supply any medicine under this protocol rests with the individual registered pharmacist who must abide by the protocol.
- Whilst pharmacy staff may support the dispensing process of the protocol, this must be carried out under the supervision of the registered pharmacist.
- Pharmacists using this SSP must ensure that it is only used within its authorised dates and within the criteria set out within the SSP. Pharmacists must check that they are using the current version of the SSP, particularly when referring to a hard copy version. Amendments may become necessary prior to the published expiry date. Current versions of SSP templates can be found at https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps.
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

Ministerial ratification by:			
Name	**Position**	**Signature**	**Date**
Maria Caulfield	Minister		19/05/2022

ADDENDUM
Supporting information on notifying other healthcare professionals

- Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.

- Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.

- Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient's prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in dispensing may take place, unless national arrangements agreed with the relevant representative bodies state otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.

- In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS Service Finder is a way for pharmacies to look up the email address of the patient's GP.

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
500microgram estradiol daily **(1 x 500microgram sachet daily)**	**25 microgram patch**	Evorel®	Apply one patch **TWICE WEEKLY**	For every 7 x 500microgram gel sachets Supply 2 Evorel® patches	Can support a partial uplift in demand
1mg estradiol daily **(2 x 500microgram sachets** **OR** **1 x 1mg sachet)**	**50 microgram patch**	Progynova TS®	Apply one patch WEEKLY	For every 14 x 500microgram gel sachets where only 500microgram gel sachets are prescribed OR For every 7 x 1mg sachets where only 1mg gel sachets are prescribed Supply 1 Progynova TS® patch	Can support a partial uplift in demand
		FemSeven®	Apply one patch WEEKLY	For every 14 x 500microgram gel sachets where only 500microgram gel sachets are prescribed OR For every 7 x 1mg sachets where only 1mg gel sachets are prescribed	Can support a partial uplift in demand

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

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