Department of Health & Social Care

NHS

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP 024

- SSP 020 – Where the duration of treatment on the prescription is for more than 3 months of estriol (Ovestin® 1mg) 0.1% cream and estriol (Ovestin® 1mg) 0.1% cream is available.
- SSP 024 **(this SSP)** – Where the duration of treatment on the prescription is for 3 months or less of estriol (Ovestin® 1mg) 0.1% cream, supplies of estriol (Ovestin® 1mg) 0.1% cream are unavailable, and substitution is deemed clinically appropriate.
- SSP 025 – Where the duration of treatment on the prescription is for more than 3 months of estriol (Ovestin® 1mg) 0.1% cream, supplies of estriol (Ovestin® 1mg) 0.1% cream are unavailable, and substitution is deemed clinically appropriate.

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Estriol (Ovestin® 1mg) 0.1% cream **where the prescription is for 3 months or less of supply and supplies are unavailable.** Where the prescription is for more than 3 months and supplies are unavailable, please refer to SSP 025. Where the prescription is for more than 3 months and supplies are available, please refer to SSP 020. **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	Estriol 0.01% cream Due to the nature of the substitution, an exact replication of the duration of treatment may not be possible.
Quantity of this formulation (if applicable)	Total quantity supplied under this protocol should be a reasonable estimate based on the current dosing regimen and quantity prescribed of estriol (Ovestin® 1mg) 0.1% cream, to be near equivalent to the number of days prescribed on the original prescription. Depending on the patient's current dose of Ovestin® 1mg cream or estriol 0.1% cream and quantity prescribed, the following must be supplied in accordance with this protocol: **estriol 0.01% cream (80g pack) – the number of packs to supply depends on the prescribed number of days of treatment on the original prescription (see doses per pack in Annex A to determine the quantity to supply)**
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 estriol (Ovestin® 1mg) 0.1% cream. • 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 estriol (Ovestin® 1mg) 0.1% cream. • 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 estriol 0.01% cream or its excipients including allergies to soya or peanuts as estriol 0.01% cream contains peanut (arachis) oil. • Patients aged less than 18 years. • If the prescription for estriol (Ovestin® 1mg) 0.1% cream received is for longer than 3 months, refer to SSP 020 where supplies are available or SSP 025 where supplies are unavailable.

Cautions including any relevant action to be taken	• Using the prescription, clarify with patients their current dosing regimen of estriol (Ovestin® 1mg) 0.1% cream to inform the duration of treatment prescribed.
	• Ensure that patients considered unsuitable for inclusion of SSP 020, 024 or 025 are promptly referred to their prescriber for further advice.
	• Assure patients of the following:
	  ○ the product they are being supplied in accordance with this SSP contains the same ingredient (estriol) as Ovestin® cream
	  ○ their dosing schedule remains the same, and they will receive the same amount of estriol per applicator dose with estriol 0.01% cream as they were receiving with Ovestin® 1mg cream. For example, if patients are currently using Ovestin® twice a week, they should use estriol 0.01% cream twice a week as directed. See **Annex A** for further information on the two products.
	  ○ clinical experts in menopause have been consulted in the production of this SSP and have advised on this approach.
	• Ensure patients are aware estriol 0.01% cream is <u>not</u> to be used if the patient is allergic to soya or peanuts.
	• 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' ○ Excessive bloating ○ Further information can be found here (NICE guidance). • Patients who experience persistent side effects from the alternative medicine supplied in accordance with this SSP should be promptly referred back to their prescriber. • 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 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:	28/10/2022
Reference number:	SSP 024
Version number:	1.1

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
1.1	Amendments to dose conversion table at Annex A	28/07/2022

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**
Lord Syed Kamall	PUSS for Technology Innovation and Life Sciences		28/07/2022

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 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
Pack size	15g (30 x 0.5g doses per pack)	80g (16 x 5g doses per pack)
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.