

**Serious Shortage Protocol (SSP) for Combisal®
(Fluticasone 125microgram / Salmeterol 25microgram)
pressurised metered dose inhaler (pMDI) – corresponding
guidance on endorsement, prescription charges,
remuneration and reimbursement plus Q&A.**

SSP034 for Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pMDI

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. The contractor must also select in the system the SSP item that has been supplied.

Example	Endorsement
<p>Example 1: Prescription for Combisal® 125microgram / 25microgram pMDI x 1</p> <p>Pharmacy contractor supplies Aloflute® 125microgram / 25microgram pMDI x 1</p>	<p>SSP034 Pharmacy contractor selects in system Aloflute® 125microgram / 25microgram pMDI x 1</p>
<p>Example 2: Prescription for Combisal® 125microgram / 25microgram pMDI x 1</p> <p>Pharmacy contractor supplies Seretide® 125 Evohaler x 1 <u>and</u> Volumatic® x 1</p>	<p>SSP034 Pharmacy contractor selects in system Seretide® 125 Evohaler x 1 <u>and</u> Volumatic® x 1</p>

Non-electronic prescription form:

Example	Endorsement
	Option

<p>Example 1: Prescription for Combisal® 125microgram / 25microgram pMDI x 1</p> <p>Pharmacy contractor supplies Aloflute® 125microgram / 25microgram pMDI x 1</p>	<p>SSP034</p> <p>Pharmacy contractor endorses Aloflute® 125microgram / 25microgram pMDI x 1</p>
<p>Example 2: Prescription for Combisal® 125microgram / 25microgram pMDI x 1</p> <p>Pharmacy contractor supplies Seretide® 125 Evohaler x 1 <u>and</u> Volumatic® x 1</p>	<p>SSP034</p> <p>Pharmacy contractor endorses Seretide® 125 Evohaler x 1 <u>and</u> Volumatic® x 1</p>

2) Prescription charges

Only one prescription charge will be applicable for patients who are not exempt from prescription charges, even where it is deemed suitable to supply an alternative spacer to the patient.

No prescription charge should be taken for the spacer where one is provided.

3) Remuneration

Supply in accordance with this SSP034 will result in the following fees being paid to the contractor:

- One Single Activity Fee (£1.27) where only one dispensed item or Two Single Activity Fees (2 x £1.27) where it is deemed suitable to supply an alternative spacer to the patient.
- One SSP fee (£5.35)

4) Reimbursement

The supplied product in accordance with this SSP034 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:

- Aloflute® 125microgram / 25microgram pMDI
- Sereflo® 125microgram / 25microgram pMDI
- Seretide® 125 Evohaler
- Sirdupla® 125microgram / 25microgram pMDI

Where deemed appropriate if a spacer is supplied in accordance with this SSP, then pharmacy contractors will be reimbursed the Part IX reimbursement price for the product endorsed. Where the correct endorsement (as per Clause 9 Part II of the Drug Tariff) is not provided,

pharmacy contractors will be reimbursed the cheapest spacer/holding chamber device as recommended for the substituted inhaler.

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 Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pMDI in England are eligible to receive an alternative supply under the terms of the SSP (only where pharmacists consider it appropriate to do so using their professional judgement).

Does the SSP apply to private prescriptions?

Yes. The scope of this SSP034 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, patients who are not exempt from prescription charges would continue to pay for this as usual. Where it is deemed suitable to supply an alternative spacer to the patient, no prescription charge should be taken for the spacer.

The only circumstance in which patients would not have to pay for a prescription charge is where an SSP recommends a lower quantity to be supplied.

Please note that the SSP for Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pMDI does not recommend a lower quantity to be supplied, so patients will continue to pay prescription charges (unless they are already exempt). For more information, please see the above guidance.

What if the product supplied is not compatible with the patient's usual spacer/holding chamber?

Where an SSP requires an alternative inhaler to be provided to a patient and the patient has been established on treatment with a spacer, the corresponding spacer should be supplied with the alternative inhaler if the original spacer that the patient has is not compatible/licensed with the substituted inhaler. In this instance any drugs or appliances which are supplied in line with a SSP, are to be reimbursed and remunerated as if they were dispensed in line with a prescription. If a new spacer needs to be provided but is supplied without the correct endorsement (as per Clause

9 Part II of the Drug Tariff) – these will be reimbursed according to the cheapest spacer/holding chamber device as recommended for the substituted inhaler.

Can any brand of spacer be supplied under this SSP?

Under this SSP, where the pharmacist deems it appropriate to supply the patient with an alternative spacer, the pharmacist must supply the compatible spacer for the substituted inhaler as listed in Annex A. Where required, the pharmacist may supply any type of spacer of the brand specified. For example, where Seretide® 125 Evohaler is supplied, the Volumatic® or the Volumatic® with paediatric mask can be supplied, where appropriate.

How should the alternative spacer be endorsed?

Where pharmacy contractors have the functionality to endorse multiple product SSPs (where multiple items are endorsed against a single prescribed item), then pharmacy contractors should select in the system that an alternative spacer has been supplied. Pharmacy contractors should endorse the spacer as per Clause 9 Part II of the Drug Tariff, detailing the brand supplied and if necessary, the type of spacer (e.g. Paediatric).

Where pharmacy contractors do not have the functionality to endorse multiple product SSPs, then the pharmacy contractor should endorse the substituted inhaler as per the usual process - contractors should endorse by selecting “SSP” and entering the three-digit reference number of the specific SSP, in addition to any other information as required under Clause 9 (apart from Clause 9C) for the substituted inhaler. However, where an alternative spacer is supplied, contractors should endorse the spacer by selecting ‘NCSO’ and entering any other information as required under Clause 9 (apart from Clause 9C) for the alternative spacer.

If contractors are not able to endorse the prescription with either of the options above, then the pharmacist should refer the patient back to their prescriber for a new prescription for an alternative inhaler and a compatible spacer device.

How would the pharmacists determine what should be supplied in accordance with this SSP?

The pharmacist will need to discuss with the patient **and** use their professional judgment when determining what should be supplied in accordance with this SSP034, taking into consideration varying ingredients and differing product licences.

Can pharmacists use their professional judgement to supply an alternative product to patients that is not listed in the SSP (e.g. dispersible tablets/ unlicensed/ special products)?

Pharmacists are not able to deviate from the options set out in the SSP as to what to supply to patients for Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pMDI. However, if pharmacists think that an alternative product not listed in this SSP 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.

Does the SSP allow for brands not listed in Annex A to be substituted?

No, only the brands and strengths of Fluticasone 125microgram / Salmeterol 25microgram pMDI listed within Annex A can be dispensed in accordance with this SSP034.

Annex A: Alternative Fluticasone 125microgram/Salmeterol 25microgram pMDIs

Alternative inhalers	Compatible spacer	Licensed age group	Contains ethanol
Fluticasone 125microgram / Salmeterol 25microgram (Aloflute [®]) pMDI	AeroChamber Plus [®]	18+	Yes
Fluticasone 125microgram / Salmeterol 25microgram (Sereflo [®]) pMDI	Manufacturer advises spacer devices are not compatible – if spacer device required switch to alternative fixed-dose combination preparation	18+	No
Fluticasone 125microgram / Salmeterol 25microgram (Seretide [®] 125 evohaler) pMDI	Volumatic [®]	12+	No
Fluticasone 125microgram / Salmeterol 25microgram (Sirdupla [®]) pMDI	AeroChamber Plus [®]	18+	Yes