

Dispensing and Supply

October 2019

PSNC Briefing 046/19: Serious Shortage Protocols (SSPs): SSP01, SSP02 & SSP03 – Fluoxetine 10mg/30mg/40mg capsules

Introduction

In response to significant ongoing disruption to the supply of fluoxetine capsules, the first Serious Shortage Protocols (SSPs) have been issued by the Department of Health and Social Care (DHSC) and these can be accessed on the NHSSAS website. This briefing provides information on these SSPs and is intended as a short guide for contractors to read in conjunction with PSNC Briefing 023/19: Serious Shortage Protocols (SSPs) — A guide for community pharmacy teams.

Each SSP allows for one or more alternatives – in this case, a different strength and/or formulation of the product – to be supplied instead of the product specified on the prescription. The dosage and period of treatment on the prescription remain the same, although the patient directions/instructions may need to be adjusted depending on the strength and/or formulation supplied. If a patient presents a prescription for either fluoxetine 10mg, 30mg, or 40mg capsules and if the product cannot be obtained, the alternatives that may be supplied in accordance with the relevant SSP are:

SSP01: Fluoxetine 10mg capsule

- 1 x Fluoxetine 10mg tablet OR
- 2.5ml of Fluoxetine 20mg/5ml oral solution OR
- 2.5ml of Fluoxetine 20mg/5ml oral solution sugar free (SF)

SSP02: Fluoxetine 30mg capsule

1 x Fluoxetine 10mg tablet PLUS 1 x Fluoxetine 20mg capsule

SSP03: Fluoxetine 40mg capsule

2 x Fluoxetine 20mg capsules

IMPORTANT: The specific SSP should be read and, subject to the conditions stated in the SSP, only an alternative set out in the specific SSP may be supplied; any other product/combination of products will require a new prescription.

The three SSPs for fluoxetine 10mg/30mg/40mg capsules commenced on 3rd October 2019 and are currently due to expire on 31st October 2019. The expiry date may be brought forward or extended, and the content may be amended throughout this period.

Pharmacists should ensure they are using the current version of an SSP before supplying an alternative product. Current versions of SSPs can be found at: www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps

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Key points

- **1.** Community pharmacy teams in receipt of prescriptions for either fluoxetine 10mg, 30mg, or 40mg capsules **must consider** the relevant SSP.
- 2. A specified alternative may be supplied if the supervising pharmacist having exercised his/her professional skill and judgement is of the opinion that the supply is **reasonable and appropriate** for the patient, and the patient agrees/consents to the alternative supply.
- **3.** There are **additional considerations** associated with supply in accordance with an SSP, for example and in brief:
 - a. Dosage should remain as originally prescribed;
 - b. Under these SSPs the **quantity of the alternative** product supplied should cover the same period of treatment as was intended by the original prescription (with the exception of fluoxetine 20mg/5ml oral solution (and SF) where **special container rules** apply);
 - c. Labelling should include 'supplied against SSP number [state number] eg 'supplied against SSP01';
 - d. Claiming/endorsement see additional guidance in Annex A below;
 - e. Record-keeping the alternative supply should be recorded on the PMR as per your usual SOPs;
 - **f. GP notification** is not required for these SSPs but may be professionally/clinically appropriate in certain circumstances;
 - **g.** Patient consent/agreement if a patient declines (or is considered unsuitable for) an alternative supply under an SSP, he or she should be promptly referred to their prescriber for further advice;
 - h. **Scope** All valid prescriptions presented in England are covered under these SSPs, including private prescriptions and those from the devolved nations; and
 - i. Criteria for inclusion and exclusion, as well as the special considerations for specific populations of patients as stated in each SSP should always be checked carefully, including:

Inclusion age

Exclusion for age

Exclusion for known previous hypersensitivity or severe adverse reaction

Exclusion for relevant hospitalisation

Exclusion related to the alternative formulation e.g. not able to swallow the tablets

Exclusion related to dosage

Consideration of any nocebo effect

Further information

The formulations of fluoxetine that are currently unobtainable have relatively low usage in England. The most frequently prescribed formulation is the 20mg capsule which PSNC understands is in good supply.

The NPA professional indemnity insurance for community pharmacy contractors applies to supplies in accordance with SSPs; contractors with other professional indemnity insurance policies should check their cover with their insurers.

Resources

<u>PSNC Briefing 023/19 (psnc.org.uk/SSPbriefing)</u> –This PSNC Briefing describes how SSPs will work in practice and provides guidance on what you need to do if an SSP is put in place.

NHSBSA SSP page (www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps) – This page will host any current and future updates on Serious Shortage Protocols from NHSBSA.

<u>PSNC SSP webinar (psnc.org.uk/SSPwebinar)</u> – This PSNC webinar details the legislation and claiming and endorsing process for SSPs. This webinar was hosted on 18th July 2019.

If you have any queries on this PSNC Briefing or you require more information, please contact:

PSNC's Dispensing and Supply Team (<u>info@psnc.org.uk</u>)

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Annex A

Endorsing prescriptions or tokens for any supplies made against SSPs

To ensure correct payments (fees and reimbursement) are made for any supplies made against these SSPs, a community pharmacy contractor is required to endorse on the paper prescription, or where issued using the Electronic Prescription Service (EPS), endorse on the electronic prescription or alternatively using the dispensing token (as outlined in Part II of the Drug Tariff) the following information:

- NCSO to indicate that the supply was made in accordance with an SSP;
- **Details of product supplied in accordance with the SSP** (drug name, quantity, strength, formulation, supplier name or brand)*;
- Quantity supplied*;
- Pack size best practice where multiple pack sizes are available; and
- Invoice price only if NHSBSA has no list-price available on dm+d.

All paper FP10 forms and EPS tokens (only where using the token for endorsement purposes) should be placed in the front of the red separator for the end-of-month submission bundle.

If submitting your claim using the EPS dispensing tokens, you must ensure your electronic reimbursement message is marked 'ND' or 'Not Dispensed'.

For SSP01, SSP02 and SSP03, DHSC has agreed to the use of abbreviated endorsements. Examples of the accepted abbreviated endorsements are illustrated in the worked examples below.

Worked examples of endorsing under an SSP

The examples in the table below show how these SSPs could be endorsed:

SSP	SSP alternative	Abbreviated endorsements permitted on original prescription or EPS token	
Fluoxetine 10mg capsules – SSP01	Fluoxetine 10mg tablets	NCSO 30 x tabs	Fluoxetine 10mg capsules 30 capsules One capsule daily
	 Fluoxetine 20mg/5ml oral solution 	NCSO 70ml solution	Fluoxetine 10mg capsules 30 capsules One capsule daily
	OR	OR	
	 Fluoxetine 20mg/5ml oral solution sugar free 	NCSO 70ml solution SF	Fluoxetine 10mg capsules 30 capsules One capsule daily

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^{*}The drug details and quantity supplied and endorsed will depend on the relevant SSP.



Fluoxetine 30mg capsules – SSP02	Fluoxetine 10mg tablets and Fluoxetine 20mg capsules	NCSO 30 x tabs 30 x caps	Fluoxetine 30mg capsules 30 capsules One capsule daily
Fluoxetine 40mg capsules – SSP03	Fluoxetine 20mg capsules	NCSO 60 x caps	Fluoxetine 40mg capsules 30 capsules One capsule daily

FAQs

Supply of Fluoxetine

Q. Can I supply and endorse the brand Prozac 20mg/5ml liquid against SSP01 for fluoxetine 10mg capsules? A. Yes. The brand Prozac may be supplied however, reimbursement would be as per the Part VIII Drug Tariff list price for the generic fluoxetine 20mg/5ml oral solution.

Q. Is fluoxetine 20mg/5ml oral solution (including sugar free) bioequivalent to fluoxetine 10mg capsules or tablets?

A. Fluoxetine 20mg/5ml oral solution has the same bioavailability as the capsules and tablets and can be used to make up the equivalent dose: 10mg = 2.5ml

Q. How do I calculate the quantity of oral solution to supply against SSP01 for fluoxetine 10mg capsules? **A.** Fluoxetine 20mg/5ml oral solution 70ml is classed as a special container; in this scenario the usual <u>special container rules</u> would still apply based on the original prescribed quantity. Special container rules state that contractors should supply the special container or combination of containers nearest to the quantity ordered. Where the quantity ordered falls exactly between two containers, the contractor should round down the quantity dispensed to the nearest complete container.

For example, where a prescription requests 30 days of fluoxetine 10mg capsules (1 capsule daily), supply of the fluoxetine 20mg/5ml oral solution in accordance with an SSP would require the pharmacist to supply 1 pack of 70ml (enough to cover 28 days treatment) based on special container rules.

Q. Can fluoxetine 20mg dispersible (Olena) tablets be considered as an alternative?

A. No. Supply of the dispersible tablets is not covered by any of the fluoxetine SSPs. A new prescription for fluoxetine 20mg dispersible tablets would need to be obtained.

Q. Can I supply fluoxetine 10mg tablets against SSP03 for fluoxetine 40mg capsules?

A. No. SSP03 for fluoxetine 40mg capsules only allows the pharmacist to supply the fluoxetine 20mg capsules.

Q. Can I obtain and supply the unlicensed fluoxetine 10mg capsules against SSP01 for (licensed) 10mg capsules?

A. No. Supply of unlicensed capsules is not covered by any SSP for any strength of fluoxetine capsules. Use of an unlicensed product needs to be determined by the prescriber. If an unlicensed product is required, the prescription would need to specify 'Fluoxetine 10mg capsules (Special Order)' and the prescription needs to be endorsed as a Non-Part VIIIB special.

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Prescription charges, fees and reimbursement

Q. How many prescription charges should be levied for a non-exempt patient for supply of two different formulations of fluoxetine (fluoxetine 10mg tablets and 20mg capsules) against SSP02 for fluoxetine 30mg capsules?

A. Only one prescription charge would apply here as this is what the patient would have paid if the original prescribed item (fluoxetine 30mg capsules) was dispensed.

When completing the end of month FP34C submission form pharmacy teams should count this as two items and treat one item as paid or 'chargeable' and the other as 'no charge'.

Q. How many SSP and Single Activity (SAF) fees does a pharmacy contractor receive for supply of fluoxetine 10mg tablets and 20mg capsules against SSP02 for fluoxetine 30mg capsules?

A. The pharmacy will receive one SSP fee and two SAFs for supplying two different presentations of fluoxetine against a single SSP.

Q. Where can I check that I have been paid for a supply of an alternative medication under an SSP?

A. The reimbursement total of SSP fees paid (including VAT) will appear on your monthly Schedule of Payment. Contractors are advised to keep a record of supplies made against SSPs to reconcile against the Schedule of Payment.

For further guidance on claiming payment for SSPs, view our factsheet: psnc.org.uk/SSPfactsheet

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