



# **SERIOUS SHORTAGE PROTOCOL (SSP)**

Reference Number: SSP044

Version Number: 1.0

## This SSP applies to the following medicine

Name of medicine (including strength and formulation)	Phenoxymethylpenicillin 125mg/5ml oral solution sugar free
	Pharmacists must ensure that the patient's prescriber and/or GP practice is notified within 24 hours when supplying a patient in accordance with this SSP.
Legal category	POM

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

Name of medicine (including formulation and strength) to be supplied	Before supplying in accordance with this SSP, the pharmacist must consider if a suitable supply can be made in accordance with SSP 040. Please see <b>Annex A</b> for the standard dosing of phenoxymethylpenicillin by age range.	
	Where it is not possible to utilise SSP 040 and where phenoxymethylpenicillin 125mg/5ml oral solution sugar free is not available and prescribed for a duration of no longer than 10 days, the following antibiotics, in order of decreasing preference, can be substituted depending on availability and the dosing needs for the patient as specified in <b>Annex B</b> .	

- Amoxicillin 125mg/5ml oral suspension
- Amoxicillin 125mg/5ml oral suspension sugar free
- Amoxicillin 250mg/5ml oral suspension
- Amoxicillin 250mg/5ml oral suspension sugar free
- Amoxicillin 250mg capsules
- Amoxicillin 500mg capsules

#### OR

- Clarithromycin 125mg/5ml oral suspension
- Clarithromycin 250mg/5ml oral suspension
- Clarithromycin 250mg tablets
- Clarithromycin 500mg tablets

#### OR

- Flucloxacillin 125mg/5ml oral solution
- Flucloxacillin 250mg/5ml oral solution
- Flucloxacillin 125mg/5ml oral solution sugar free
- Flucloxacillin 250mg/5ml oral solution sugar free
- Flucloxacillin 250mg capsules
- Flucloxacillin 500mg capsules

## OR

(Broader spectrum antibiotics with increased risks of side effects and antimicrobial resistance – reserve for when alternatives unavailable.)

- Cefalexin 125mg/5ml oral suspension
- Cefalexin 125mg/5ml oral suspension sugar free
- Cefalexin 250mg/5ml oral suspension
- Cefalexin 250mg/5ml oral suspension sugar free
- Cefalexin 250mg capsules
- Cefalexin 250mg tablets
- Cefalexin 500mg capsules
- Cefalexin 500mg tablets

OR

(Broader spectrum antibiotics with increased risks of side effects and antimicrobial resistance – reserve for when alternatives unavailable.)

- Co-amoxiclav 125mg/31mg/5ml oral suspension
- Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
- Co-amoxiclav 250mg/62mg/5ml oral suspension
- Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
- Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
- Co-amoxiclav 250mg/125mg tablets
- Co-amoxiclav 500mg/125mg tablets

For prescriptions for phenoxymethylpenicillin 125mg/5ml oral solution sugar free **longer than 10 days**, the preferred substitution is one of the following erythromycin formulations, with reference to **Annex C** for dosing information. In the event erythromycin is unavailable in a suitable formulation/dosage, pharmacists should refer the patient back to the prescriber.

- Erythromycin 125mg/5ml oral suspension
- Erythromycin 125mg/5ml oral suspension sugar free
- Erythromycin 250mg/5ml oral suspension
- Erythromycin 250mg/5ml oral suspension sugar free
- Erythromycin 250mg gastro-resistant tablets
- Erythromycin 250mg tablets
- Erythromycin 500mg tablets

# Quantity of this formulation

Total quantity supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription. The quantity supplied may be different due to different dosing regimens for different antibiotics.

For the substituted antibiotic, the quantity and strength supplied is to be determined by the recommended dosing regimen as set out in **Annex B and C** accordingly.

# Substitution results in a change to whether the use is licenced

No. However, if tablets/ capsules must be manipulated in some way by patients to be ingested (e.g. crushed/ dispersed) then yes. Please refer to the guidance on using solid oral dosage form antibiotics in children included in the addendum at the end of this form.

## Scope for which this Serious Shortage Protocol (SSP) applies

The SSP applies to the following parts of the UK	
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## Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	All NHS and private prescriptions.  This protocol does not allow the number of days treatment to be less than what was prescribed on the original prescription, although supply might be split between more than one dispensing episode in case of owings to ensure the patient can commence treatment without delay.		
Criteria for inclusion	<ul> <li>The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for phenoxymethylpenicillin 125mg/5ml oral solution sugar free.</li> <li>The patient/carer consents to receiving the medicine supplied in accordance with this SSP.</li> </ul>		
Criteria for exclusion	<ul> <li>Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive an alternative medicine in accordance with this SSP.</li> <li>The patient presents with a prescription for a medicine other than phenoxymethylpenicillin 125mg/5ml oral solution sugar free.</li> <li>The patient presents a prescription which is not valid.</li> <li>The patient/carer does not consent to receiving the medicine(s) supplied in accordance with this SSP.</li> <li>Patients who have had a previous allergic reaction to the alternative options or their excipients.</li> <li>Children on a ketogenic diet for epilepsy.</li> </ul>		
Cautions including any relevant action to be taken	If supplying the tablet/capsule form, the pharmacist should be satisfied that the patient is able to accommodate the switch from liquid to tablet/capsule. Please refer to the guidance on how to give solid oral dosage forms to children included in the addendum at the end of this form. Please note that use in this way may be outside the product licence and is thus "off-label".		

Special considerations for specific populations of patients	<ul> <li>When determining the dose of the alternative antibiotic to be supplied, where appropriate, pharmacists must take into account the body weight of babies and children as specified in Annex B. The pharmacist should confirm the patient's weight with their parent/carer and refer to their personal child health record ('red book') where possible.</li> <li>If the prescribed phenoxymethylpenicillin dose is higher than the standard doses within Annex A, then the pharmacist should consult the prescriber to confirm the substitution and dosing requirement.</li> <li>For diabetic patients, pharmacists should supply sugar free options where possible. If this is not available, patients/carers should be informed that there is a small amount of sugar contained in the product supplied, but do not withhold treatment.</li> <li>Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.</li> <li>Potential contra-indications to, or interactions between the patient's existing medications with the substituted product should be checked prior to substituting from the above list.</li> <li>Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive the alternative medicine in accordance with this SSP.</li> </ul>
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 in accordance with this SSP, then they should be referred back to their prescriber promptly.

Valid from:	16/12/2022
Expiry date:	31/01/2023
Reference number:	SSP044
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: <a href="mailto:nhsbsa.prescriptionservices@nhsbsa.nhs.uk">nhsbsa.prescriptionservices@nhsbsa.nhs.uk</a>

**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 in accordance with 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 <a href="https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps">https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps</a>.
- 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	
William Quince	Minister of State	Wilm In-	16/12/2022	

## **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.

## Switching from liquid to solid phenoxymethylpenicillin

When the medicine is for a child and the pharmacist deems it appropriate to substitute
to the tablet form in accordance with this SSP, patients/carers should be directed to
the following guidance: <u>Using solid oral dosage form antibiotics in children - SPS -</u>
Specialist Pharmacy Service

## Annex A- Standard dosing of phenoxymethylpenicillin by age range

Age range	Phenoxymethylpenicillin dose
1-11 months	62.5mg four times a day or 125mg twice a day.
1-5 years	125mg four times a day or 250mg twice a day.
6-11 years	250mg four times a day or 500mg twice a day.
12-17 years	500mg four times a day or 1000mg twice a day.
Adult	500mg four times a day or 1000mg twice a day.

## Annex B- Alternative antibiotic products and dosing information

The total quantity to be supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription.

Alternative product	Age	Usual treatment dose	Available formulations	Interactions and side effects
Amoxicillin	1-11 months	125mg three times a day.	Amoxicillin 125mg/5ml oral suspension	Interactions Side effects
Amoxicillin	1-4 years	250mg three times a day	Amoxicillin 125mg/5ml oral suspension sugar free	
Amoxicillin	5-17 years and adult	500mg three times a day.	<ul> <li>Amoxicillin 250mg/5ml oral suspension</li> <li>Amoxicillin 250mg/5ml oral suspension sugar free</li> <li>Amoxicillin 250mg capsules</li> <li>Amoxicillin 500mg capsules</li> </ul>	
Clarithromycin	1 month- 11 years (body weight up to 8kg)	7.5mg/kg twice daily.	<ul> <li>Clarithromycin 250mg tablets</li> <li>Clarithromycin 125mg/5ml oral suspension</li> </ul>	Interactions Side effects
Clarithromycin	1 month- 11 years (body weight 8-11kg)	62.5mg twice daily.	Clarithromycin 250mg/5ml oral suspension	

Clarithromycin	1 month- 11 years (body weight 12- 19kg) 1 month- 11 years (body weight 20-	125mg twice daily.  187.5mg twice daily.	Clarithromycin 500mg tablets		
Clarithromycin	29kg) 1 month- 11 years (body weight 30- 40kg)	250mg twice daily.			
Clarithromycin	12-17 years and adult	250mg twice daily.			
Cefalexin	1-11 months	125 mg twice daily.		in 250mg capsules in 500mg capsules	Interactions Side effects
Cefalexin	1-4 years	125 mg three times a day.		in 500mg tablets in 125mg/5ml oral	
Cefalexin	5-11 years	250 mg three times a day.	suspens Cefalex	sion in 125mg/5ml oral	
Cefalexin	12-17 years	500 mg twice a day.	•	suspension sugar free Cefalexin 250mg/5ml oral	
Cefalexin	Adult	250 mg every 6 hours, OR 500 mg every 12 hours.	suspensior Cefalexin 2		
Flucloxacillin	1 month - 1 year	62.5mg four times a day.	Flucloxa capsule	acillin 250mg es	Interactions Side effects
Flucloxacillin	2-9 years	125mg four times a day.	<ul> <li>Flucloxacillin 500mg         capsules</li> <li>Flucloxacillin 125mg/5ml         oral solution</li> <li>Flucloxacillin 125mg/5ml         oral solution sugar free</li> <li>Flucloxacillin 250mg/5ml         capsules oral solution         Flucloxacillin 250mg/5ml         capsules oral solution sugar         free</li> </ul>	9	
Flucloxacillin	10-17 years	250mg four times a day.			
Flucloxacillin	Adult	250mg four times a day.		acillin 125mg/5ml ution sugar free acillin 250mg/5ml es oral solution acillin 250mg/5ml	
Co-amoxiclav	1-11 months 2 – 23 months	125mg/31mg per 5ml suspension - 0.25mL/kg three times a day. 400mg/57mg per 5ml suspension- 0.15mL/kg twice daily.	per 5ml Co-amo per 5ml sugar fr Co-amo	oxiclav 250mg/62mg	Interactions Side effects
Co-amoxiclav	1-5 years	<b>125mg/31mg per 5ml suspension</b> - 0.25mL/kg three times a day.	per 5ml	l oral suspension	

	2-6 years (body weight 13-21kg)	<b>400mg/57mg per 5ml</b> <b>suspension-</b> 2.5mL twice daily.	Co-amoxiclav 250mg/62mg     per 5ml oral suspension     sugar free
Co-amoxiclav	6-11 years 7 – 12 years (body weight 22	250mg/62mg per 5ml suspension – 5mL three times a day. 400mg/57mg per 5ml suspension- 5mL twice	<ul> <li>Co-amoxiclav 400mg per 57mg per 5ml oral suspension sugar free</li> <li>Co-amoxiclav 250mg/125mg tablets</li> </ul>
Co-amoxiclav	- 40kg)  12-17 years  12 - 17 years (body weight 41kg and above)	daily.  250/125 mg tablet- 1 tablet every 8 hours.  400mg/57mg per 5ml suspension- 10mL twice	• Co-amoxiclav 500mg/125mg tablets
Co-amoxiclav	Adult	daily.  250/125 mg tablet- 1 tablet every eight hours.  400mg/57mg per 5ml suspension- 10mL twice daily.	

# Annex C - For patients receiving phenoxymethylpenicillin for long term prophylaxis offer erythromycin as per below:

The total quantity to be supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription.

Alternative product	Age	Dose	Available formulations	Interactions
Erythromycin	3 months up to 1 year	62.5mg twice a day.	<ul> <li>Erythromycin stearate 250mg tablets</li> </ul>	Interactions Side effects
Erythromycin	1 year up to 5 years	125mg twice a day.	<ul> <li>Erythromycin stearate 500mg tablets</li> <li>Erythromycin 250mg gastroresistant tablets</li> <li>Erythromycin ethyl succinate 500mg tablets</li> <li>Erythromycin ethyl succinate 125mg/5ml oral suspension</li> <li>Erythromycin ethyl succinate 125mg/5ml oral suspension sugar free</li> <li>Erythromycin ethyl succinate 250mg/5ml oral suspension</li> <li>Erythromycin ethyl succinate 250mg/5ml oral suspension sugar free</li> </ul>	
Erythromycin	5 years and above	250mg twice a day.		

	<ul> <li>Erythromycin ethyl succinate 500mg/5ml oral suspension</li> <li>Erythromycin ethyl succinate 500mg/5ml oral suspension sugar free</li> </ul>
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