



SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP043

Version Number: 1.2

This SSP applies to the following medicine

Name of medicine (including strength and formulation)	Phenoxymethylpenicillin 125mg/5ml oral solution <u>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.</u>
Legal category	POM

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	<p>Please see Annex A for the standard dosing of phenoxymethylpenicillin by age range.</p> <p>Where phenoxymethylpenicillin 125mg/5ml oral solution 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 Annex B.</p> <ul style="list-style-type: none">• 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
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- Amoxicillin 500mg capsules

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

	<p>For prescriptions for phenoxymethylpenicillin 125mg/5ml oral solution 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.</p> <ul style="list-style-type: none"> • 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
<p>Quantity of this formulation</p>	<p>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.</p> <p>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.</p>
<p>Substitution results in a change to whether the use is licenced</p>	<p>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.</p>

Scope for which this Serious Shortage Protocol (SSP) applies

<p>The SSP applies to the following parts of the UK</p>	<p>UK-wide</p>
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Clinical situation to which this Serious Shortage Protocol (SSP) applies

<p>Scope of SSP</p>	<p>All NHS and private prescriptions.</p> <p>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 omissions to ensure the patient can commence treatment without delay.</p>
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<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> • The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for phenoxymethylpenicillin 125mg/5ml oral solution. • The patient/carer consents to receiving the medicine supplied in accordance with this SSP.
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> • Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive an alternative medicine in accordance with this SSP. • The patient presents with a prescription for a medicine other than phenoxymethylpenicillin 125mg/5ml oral solution. • The patient presents a prescription which is not valid. • The patient/carer does not consent to receiving the medicine(s) supplied in accordance with this SSP. • Patients who have had a previous allergic reaction to the alternative options or their excipients. • Children on a ketogenic diet for epilepsy.
<p>Cautions including any relevant action to be taken</p>	<ul style="list-style-type: none"> • 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”. • 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. • 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. • 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. • Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.

	<ul style="list-style-type: none"> 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.
Special considerations for specific populations of patients	Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive the alternative medicine in accordance with this SSP.
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:	28/02/2023
Reference number:	SSP043
Version number:	1.2

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
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1.1	Addition of azithromycin as an antibiotic option	23/12/22
1.2	Removal of clarithromycin and azithromycin	23/01/23

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 <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
William Quince	Minister of State		31/01/2023

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

- 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: [Using solid oral dosage form antibiotics in children - SPS - 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.	<ul style="list-style-type: none"> 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 	Interactions Side effects
Amoxicillin	1-4 years	250mg three times a day		
Amoxicillin	5-17 years and adult	500mg three times a day.		
Flucloxacillin	1 month - 1 year	62.5mg four times a day.	<ul style="list-style-type: none"> Flucloxacillin 250mg capsules Flucloxacillin 500mg capsules Flucloxacillin 125mg/5ml oral solution Flucloxacillin 125mg/5ml oral solution sugar free Flucloxacillin 250mg/5ml capsules oral solution Flucloxacillin 250mg/5ml capsules oral solution sugar free 	Interactions Side effects
Flucloxacillin	2-9 years	125mg four times a day.		
Flucloxacillin	10-17 years	250mg four times a day.		
Flucloxacillin	Adult	250mg four times a day.		
Cefalexin	1-11 months	125 mg twice daily.	<ul style="list-style-type: none"> Cefalexin 250mg capsules Cefalexin 500mg capsules Cefalexin 500mg tablets 	Interactions Side effects
Cefalexin	1-4 years	125 mg three times a day.		

Cefalexin	5-11 years	250 mg three times a day.	<ul style="list-style-type: none"> • 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	12-17 years	500 mg twice a day.		
Cefalexin	Adult	250 mg every 6 hours, OR 500 mg every 12 hours.		
Co-amoxiclav	1-11 months	125mg/31mg per 5ml suspension - 0.25mL/kg three times a day.	<ul style="list-style-type: none"> • Co-amoxiclav 125mg/31mg per 5ml oral suspension • Co-amoxiclav 125mg/31mg per 5ml oral suspension sugar free • Co-amoxiclav 250mg/62mg per 5ml oral suspension • Co-amoxiclav 250mg/62mg per 5ml oral suspension sugar free • Co-amoxiclav 400mg per 57mg per 5ml oral suspension sugar free • Co-amoxiclav 250mg/125mg tablets • Co-amoxiclav 500mg/125mg tablets 	Interactions Side effects
		2 – 23 months		
Co-amoxiclav	1-5 years	125mg/31mg per 5ml suspension - 0.25mL/kg three times a day.		
	2-6 years (body weight 13-21kg)	400mg/57mg per 5ml suspension - 2.5mL twice daily.		
Co-amoxiclav	6-11 years	250mg/62mg per 5ml suspension – 5mL three times a day.		
	7 – 12 years (body weight 22 – 40kg)	400mg/57mg per 5ml suspension - 5mL twice daily.		
Co-amoxiclav	12-17 years	250/125 mg tablet - 1 tablet every 8 hours.		
	12 – 17 years (body weight 41kg and above)	400mg/57mg per 5ml suspension - 10mL twice daily.		
Co-amoxiclav	Adult	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	1-23 months	125mg twice a day.	<ul style="list-style-type: none"> Erythromycin stearate 250mg tablets 	Interactions Side effects
Erythromycin	2 years up to 7 years	250mg twice a day.	<ul style="list-style-type: none"> Erythromycin stearate 500mg tablets 	
Erythromycin	8 years – 17 years and adult	500mg twice a day.	<ul style="list-style-type: none"> Erythromycin 250mg gastro-resistant tablets Erythromycin ethyl succinate 500mg tablets Erythromycin ethyl succinate 125mg/5ml oral suspension Erythromycin ethyl succinate 125mg/5ml oral suspension sugar free Erythromycin ethyl succinate 250mg/5ml oral suspension Erythromycin ethyl succinate 250mg/5ml oral suspension sugar free Erythromycin ethyl succinate 500mg/5ml oral suspension Erythromycin ethyl succinate 500mg/5ml oral suspension sugar free 	