



## SERIOUS SHORTAGE PROTOCOL (SSP)

#### Reference Number: SSP045

Version Number: 1.0

#### This SSP applies to the following medicine

| Name of medicine<br>(including strength and<br>formulation) | Phenoxymethylpenicillin 250mg/5ml oral solution<br>Pharmacists must ensure that the patient's prescriber<br>and/or GP practice is notified within 24 hours when<br>supplying a patient in accordance with this SSP. |
|---|---|
| Legal category  | POM   |

1. Details of medication to be supplied under this SSP

| Name of medicine<br>(including formulation and<br>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 042. Please see <b>Annex A</b> for the standard dosing of phenoxymethylpenicillin by age range.  |
|--|---|
|  | Where it is not possible to utilise SSP042 and where<br>phenoxymethylpenicillin 250mg/5ml oral solution is not<br>available and prescribed for a duration of no longer than<br>10 days, the following antibiotics, in order of decreasing<br>preference, can be substituted depending on availability<br>and the dosing needs for the patient as specified in<br><b>Annex B</b> . |
|  | Amoxicillin 125mg/5ml oral suspension   |

| <ul> <li>Amoxicillin 125mg/5ml oral suspension sugar free</li> <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> <li>OR</li> <li>Clarithromycin 125mg/5ml oral suspension</li> </ul> |
|---|
| <ul> <li>Clarithromycin 250mg/5ml oral suspension</li> <li>Clarithromycin 250mg tablets</li> <li>Clarithromycin 500mg tablets</li> </ul>  |
| OR  |
| <ul> <li>Flucloxacillin 125mg/5ml oral solution</li> <li>Flucloxacillin 250mg/5ml oral solution</li> <li>Flucloxacillin 125mg/5ml oral solution sugar free</li> <li>Flucloxacillin 250mg/5ml oral solution sugar free</li> <li>Flucloxacillin 250mg capsules</li> <li>Flucloxacillin 500mg capsules</li> </ul>      |
| OR  |
| (Broader spectrum antibiotics with increased risks of side effects and antimicrobial resistance – reserve for when alternatives unavailable.)   |
| <ul> <li>Cefalexin 125mg/5ml oral suspension</li> <li>Cefalexin 125mg/5ml oral suspension sugar free</li> </ul>   |
| Cefalexin 250mg/5ml oral suspension   |
| <ul> <li>Cefalexin 250mg/5ml oral suspension sugar free</li> <li>Cefalexin 250mg capsules</li> </ul>  |
| <ul> <li>Cefalexin 250mg tablets</li> </ul>   |
| Cefalexin 500mg capsules  |
| Cefalexin 500mg tablets   |
| OR  |

|   | <ul> <li>(Broader spectrum antibiotics with increased risks of side effects and antimicrobial resistance – reserve for when alternatives unavailable.)</li> <li>Co-amoxiclav 125mg/31mg/5ml oral suspension</li> <li>Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free</li> <li>Co-amoxiclav 250mg/62mg/5ml oral suspension</li> <li>Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free</li> <li>Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free</li> </ul> |
|---|---|
|   | <ul> <li>Co-amoxiclav 250mg/125mg tablets</li> <li>Co-amoxiclav 500mg/125mg tablets</li> </ul>  |
|   | For prescriptions of phenoxymethylpenicillin 250mg/5ml<br>oral solution <b>longer than 10 days</b> , the preferred<br>substitution is one of the following erythromycin<br>formulations, with reference to <b>Annex C</b> for dosing<br>information. In the event erythromycin is unavailable in a<br>suitable formulation/dosage, pharmacists should refer the<br>patient back to the prescriber.  |
|   | <ul> <li>Erythromycin 125mg/5ml oral suspension</li> <li>Erythromycin 125mg/5ml oral suspension sugar free</li> <li>Erythromycin 250mg/5ml oral suspension</li> <li>Erythromycin 250mg/5ml oral suspension sugar free</li> <li>Erythromycin 250mg gastro-resistant tablets</li> <li>Erythromycin 250mg tablets</li> <li>Erythromycin 500mg tablets</li> </ul>   |
| Quantity of this formulation                                    | Total quantity supplied in accordance with this protocol is<br>to be equivalent to the number of days treatment<br>prescribed on the original prescription. The quantity<br>supplied may be different due to different dosing<br>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 <b>Annex B and C</b> accordingly.  |
| Substitution results in a change to whether the use is licenced | No. However, if tablets/ capsules must be manipulated in<br>some way by patients to be ingested (e.g. crushed/<br>dispersed) then yes. Please refer to the guidance on<br>using solid oral dosage form antibiotics in children<br>included in the addendum at the end of this form.   |

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

| The SSP applies to the<br>following parts of the UKUK-wide |
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|--|

## Clinical situation to which this Serious Shortage Protocol (SSP) applies

| Scope of SSP                                       | All NHS and private prescriptions.<br>This protocol does not allow the number of days<br>treatment to be less than what was prescribed on the<br>original prescription, although supply might be split<br>between more than one dispensing episode in case of<br>owings to ensure the patient can commence treatment<br>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 250mg/5ml oral solution.</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 250mg/5ml oral solution.</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 | <ul> <li>If supplying the tablet/capsule form, the pharmacist<br/>should be satisfied that the patient is able to<br/>accommodate the switch from liquid to tablet/capsule.<br/>Please refer to the guidance on how to give solid oral<br/>dosage forms to children included in the addendum at<br/>the end of this form. Please note that use in this way<br/>may be outside the product licence and is thus "off-<br/>label".</li> </ul>   |  |

| 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> </ul> |
|--|--|
| Action to be taken if the patient is excluded                  | If a patient does not meet the criteria within this SSP then<br>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: | SSP045     |
| 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: <u>nhsbsa.prescriptionservices@nhsbsa.nhs.uk</u> Telephone: 0300 330 1349 Textphone: 18001 0300 330 1349

You can also write to us at:

| Newcastle   | Middlebrook  | Wakefield   |
|---|--|---|
| NHS Prescription Services<br>Bridge House<br>152 Pilgrim Street<br>Newcastle upon Tyne<br>NE1 6SN | NHS Prescription Services<br>Ridgway House<br>Northgate Close<br>Middlebrook<br>Horwich<br>Bolton<br>BL6 6PQ | NHS Prescription Services<br>4th Floor<br>Wakefield House<br>Borough Road<br>Wakefield<br>WF1 3UB |

#### Change history

| Version<br>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 | Wilson Ima | 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> <u>Specialist Pharmacy Service</u>

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

| Clarithromycin<br>Clarithromycin<br>Clarithromycin | 1 month- 11<br>years (body<br>weight 12-<br>19kg)<br>1 month- 11<br>years (body<br>weight 20-<br>29kg)<br>1 month- 11 | 125mg twice daily.<br>187.5mg twice daily.<br>250mg twice daily.  | Clarithromycin 500mg     tablets  |
|--|---|---|---|
| Clavithur music                                    | years (body<br>weight 30-<br>40kg)  | 250mg tuise deilu   |   |
| Clarithromycin                                     | 12-17 years and adult   | 250mg twice daily.  |   |
| Cefalexin  | 1-11 months   | 125 mg twice daily.   | <ul> <li>Cefalexin 250mg capsules</li> <li>Cefalexin 500mg capsules</li> <li>Side effects</li> </ul>  |
| Cefalexin  | 1-4 years   | 125 mg three times a day.   | <ul><li>Cefalexin 500mg tablets</li><li>Cefalexin 125mg/5ml oral</li></ul>  |
| Cefalexin  | 5-11 years  | 250 mg three times a day.   | <ul><li>suspension</li><li>Cefalexin 125mg/5ml oral</li></ul>   |
| Cefalexin  | 12-17 years   | 500 mg twice a day.   | <ul><li>suspension sugar free</li><li>Cefalexin 250mg/5ml oral</li></ul>  |
| Cefalexin  | Adult   | 250 mg every 6 hours,<br>OR 500 mg every<br>12 hours.   | <ul> <li>suspension</li> <li>Cefalexin 250mg/5ml oral suspension sugar free</li> </ul>  |
| Flucloxacillin                                     | 1 month - 1<br>year   | 62.5mg four times a day.  | Flucloxacillin 250mg <u>Interactions</u> <u>Side effects</u>  |
| Flucloxacillin                                     | 2-9 years   | 125mg four times a day.   | Flucloxacillin 500mg     capsules   |
| Flucloxacillin                                     | 10-17 years   | 250mg four times a day.   | Flucloxacillin 125mg/5ml     oral solution  |
| Flucloxacillin                                     | Adult   | 250mg four times a day.   | <ul> <li>Flucloxacillin 125mg/5ml<br/>oral solution sugar free</li> <li>Flucloxacillin 250mg/5ml<br/>capsules oral solution<br/>Flucloxacillin 250mg/5ml<br/>capsules oral solution sugar<br/>free</li> </ul> |
| Co-amoxiclav                                       | 1-11 months<br>2 – 23 months  | 125mg/31mg per 5ml<br>suspension - 0.25mL/kg<br>three times a day.<br>400mg/57mg per 5ml<br>suspension- 0.15mL/kg<br>twice daily. | <ul> <li>Co-amoxiclav 125mg/31mg<br/>per 5ml oral suspension</li> <li>Co-amoxiclav 125mg/31mg<br/>per 5ml oral suspension<br/>sugar free</li> <li>Co-amoxiclav 250mg/62mg</li> </ul>                          |
| Co-amoxiclav                                       | 1-5 years   | <b>125mg/31mg per 5ml</b><br><b>suspension</b> - 0.25mL/kg<br>three times a day.  | per 5ml oral suspension   |

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

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