

MODEL STANDING DRUG ORDER

Secondary prophylaxis for the prevention of recurrent acute rheumatic fever - Benzathine benzylpenicillin G (Bicillin L-A[®])

Introduction

A Model Standing Drug Order (SDO) for secondary prophylaxis for the prevention of recurrent acute rheumatic fever - Benzathine benzylpenicillin G (Bicillin L-A[®]) has been developed by the South Australian Rheumatic Heart Disease Control Program as a sample for use by health services in the development of their own SDO to support nurse initiated benzathine benzylpenicillin G (Bicillin L-A[®]) administration.

Model Standing Drug Orders (SDOs) provide an organisation the mechanism to enable an authorised person to autonomously handle and administer specific Schedule 4 drugs, in this case benzathine benzylpenicillin G (Bicillin L-A[®]), without a prescribed medication order by a medical officer.

The information contained in the Model SDO is consistent with the recommendations contained in the *Australian guideline for the prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (3rd edition)* and the Australian Medicines Handbook.

Standing drug orders are intended for use by healthcare personnel working within their scope of practice as determined by their health practitioner registration and by the employing health service.

Registered Nurses/Midwives (RN/M), Enrolled Nurses (EN) and Aboriginal Health Practitioners (AHP) are unable to initiate and administer benzathine benzylpenicillin G (Bicillin L-A[®]) until the Model SDO has been authorised by the endorsement committee within the organisation.

This Model SDO should only be implemented if your health service has its own local procedure/guideline in place for managing anaphylaxis, including access to adrenaline.

Endorsement Committee

The Model SDO must be signed by the endorsement committee, including the name and title of each committee member.

The endorsement committee should consist of a medical officer, senior nurse and a manager (usually the CEO or Unit Manager). In some circumstances a pharmacist may also be included; however the pharmacist cannot replace the medical officer.

The endorsement committee is responsible for the:

- implementation of the SDO
- ongoing review and endorsement of the SDO as required
- development and monitoring of health service policies and procedures within the organisation.

MODEL STANDING DRUG ORDER

Secondary prophylaxis for the prevention of recurrent acute rheumatic fever - Benzathine benzylpenicillin G (Bicillin L-A®)

How to implement this model SDO in your organisation

To be valid the SDO must:

- a) be printed on the individual organisation's letterhead or a covering letter on the organisation's letterhead must accompany the signed Model SDO;
- b) have the relevant signatures completed for the SDO on the sign-off page; and
- c) be read, understood and signed by each nurse administering benzathine benzylpenicillin G (Bicillin L-A®) within the organisation.

Please note: Any handwritten amendments to the SDO after the signatures have been added will invalidate the SDO.

For further information that is not contained in the SDO, please call the Rheumatic Heart Disease Control Program on 08 7425 7146 or the medical officer who endorsed the SDO.

References

1. The 2020 guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (3rd edition). Available from www.rhdaustralia.org.au.
2. Australian Medicines Handbook Pty Ltd. Last modified July 2022
3. Australian Injectable Drugs Handbook (8th edition) 2020
4. Health Practitioner Regulation National Law (SA) Act 2010
5. Controlled Substances Act 1984 (and its Regulations)
6. Consent to Medical Treatment and Palliative Care Act 1995
7. Nursing and Midwifery Board of Australia (NMBA) Standards for Practice
8. Aboriginal and Torres Strait Islander Health Practice Board of Australia (ATSIHPBA).



Government of South Australia
SA Health



TEMPLATE STANDING DRUG ORDER (SDO)

Title	Secondary prophylaxis for the prevention of recurrent acute rheumatic fever Benzathine benzylpenicillin tetrahydrate (Bicillin[®] L-A)
Location	www.sahealth.sa.gov.au/rhd
Date Reviewed	14 June 2024
Next Due Date for Review	14 June 2026
Author	Communicable Disease Control Branch
Person Responsible	Noel Lally
Position	Executive Director
References	<ol style="list-style-type: none">1. The 2020 guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (3rd edition) (the Guideline). Available from www.rhdaustralia.org.au.2. Australian Medicines Handbook Pty Ltd. Last modified July 20223. Australian Injectable Drugs Handbook (8th edition) 20204. Health Practitioner Regulation National Law (South Australia) Act 20105. Controlled Substances Act 1984 (and its Regulations)6. Consent to Medical Treatment and Palliative Care Act 19957. Nursing and Midwifery Board of Australia (NMBA) Standards for Practice8. Australian Product Information – Bicillin® L-A (benzathine benzylpenicillin tetrahydrate) suspension for injection. Available from https://www.tga.gov.au

APPLICATION OF TEMPLATE STANDING DRUG ORDER

1. Clinical practice areas where template SDO can be used	Any primary health care service conducted by a Local Government, Community Health Centre, Hospital, Aboriginal Health Service, Royal Flying Doctor Service or any other health service in South Australia (SA).
--	---

ENDORSEMENT COMMITTEE – MEDICAL OFFICER, SENIOR NURSE AND MANAGEMENT

Name – Signature: _____ Title: _____ Date: _____

Name – Signature: _____ Title: _____ Date: _____

Name – Signature: _____ Title: _____ Date: _____

AUTHORISATION

This template Standing Drug Order (SDO) authorises appropriately qualified staff that have read and understood the following information to administer benzathine benzylpenicillin (Bicillin L-A), for the prevention of acute rheumatic fever as below:

Benzathine benzylpenicillin (Bicillin L-A)

Single dose intramuscular injection:

- **1,200,000 units for all persons who weigh \geq 20 kg.**
- **600,000 units for persons who weigh $<$ 20 kg.**

Note: this template SDO is specific for Bicillin L-A and not applicable to other formulations of benzathine benzylpenicillin

STAFF AUTHORISATION**2. Staff credentialing requirements****2.1 Registered Nurse or Midwife**

- 2.1.1 Accountable and responsible for own actions within nursing practice in accordance with the Nursing and Midwifery Board of Australia (NMBA) Registered nurse standards for practice - effective 1 June 2016 and the Midwifery competency standards – effective January 2006
- 2.1.2 Practices in accordance with Division 8, Subdivision 1, section 94 (1) *Health Practitioner Regulation National Law (South Australia) Act 2010*
- 2.1.3 Holds current Certificate of Registration with the NMBA
- 2.1.4 Compliant with organisational standards, policies, and procedures
- 2.1.5 Compliant with all relevant legislation and guidelines
- 2.1.6 Has completed certificate in cardio-pulmonary resuscitation (CPR) within the last 12 months.

2.2 Enrolled Nurse

Can administer intramuscular antibiotics if they can demonstrate ALL of the following:

- 2.2.1 Have received delegation from a registered nurse/midwife.
- 2.2.2 Competence to practice and is responsible for own actions in accordance with the NMBA Enrolled nurse standards for practice - effective 1 January 2016
- 2.2.3 Compliance with organisational standards, policies, and procedures
- 2.2.4 Compliance with all relevant legislation and guidelines
- 2.2.5 Practices in accordance with Division 8, Subdivision 1, section 94 (1) *Health Practitioner Regulation National Law (South Australia) Act 2010*
- 2.2.6 Assessment of the client by a registered nurse/midwife or medical practitioner prior to administration
- 2.2.7 Direct or indirect supervision by a registered nurse or midwife
- 2.2.8 Current Certificate of Enrolment with the NMBA
- 2.2.9 Certificate in CPR within the last 12 months

2.3 Aboriginal Health Practitioner

Can administer intramuscular antibiotics if they can demonstrate ALL of the following:

- 2.3.1 Have received delegation from a medical practitioner or registered nurse/midwife.
- 2.3.2 Compliance with organisational standards, policies, and procedures
- 2.3.3 Compliance with clinical governance frameworks and the organisation's scope of practice
- 2.3.4 Compliance with all relevant legislation and guidelines
- 2.3.5 Assessment of the client by a registered nurse/midwife or medical practitioner prior to administration
- 2.3.6 Direct or indirect supervision by a registered nurse/midwife
- 2.3.7 Current Certificate with the Aboriginal and Torres Strait Islander Health Practice Board of Australia
- 2.3.8 Certificate in CPR within the last 12 months

<p>3. Background</p>	<p>3.1 Acute rheumatic fever (ARF) is an illness caused by a reaction to a bacterial infection with group A streptococcus (GAS). ARF damages the valves of the heart. People who have had ARF once are more likely to get it again. The more often they have ARF the greater the chance of damage to their heart. Damage to heart valves caused by ARF is called rheumatic heart disease (RHD). All people with a diagnosis of ARF or RHD should be assessed by a medical practitioner and commenced on a management plan. For most people this includes a regular intramuscular injection of benzathine benzylpenicillin Bicillin L-A every 4 weeks for at least five years. The use of regular benzathine benzylpenicillin Bicillin L-A helps to prevent GAS infection that can lead to recurrent ARF and further damage to the heart; this is known as secondary prophylaxis. Missing doses increases the risk of another GAS infection and more heart damage.</p> <p>3.2 This template SDO is only to be used for patients who have had a diagnosis of ARF or have RHD, who have been commenced by a medical practitioner on a management plan including secondary prophylaxis with regular intramuscular Bicillin L-A. This information must be confirmed from at least two of the following three options:</p> <ul style="list-style-type: none"> • The patient confirms they are having regular Bicillin L-A injections. • It is confirmed through contact with a registered nurse or general practitioner from the patient's usual health service where the patient has a current management plan that includes regular Bicillin L-A injections. • It is confirmed through information contained on the RHD Register (RHD Register contact number 08 7425 7146) that the patient has a current management plan that includes regular Bicillin L-A injections. <p>3.3 This template SDO will not meet the need of all patients and must always be used in conjunction with the 2020 Australian guideline for the prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease, 3rd edition (the Guideline).</p> <p>3.4 Clinical assessment and advice from a medical practitioner should be sought if the recommendations for a specific clinical situation cannot be determined using the template SDO together with the Guideline.</p> <p>3.5 Refer to Appendix A of the Guideline for information on other options for pain minimisation for the delivery of Bicillin L-A. Note, Bicillin L-A can be administered with lidocaine and a separate standing drug order is available for this.</p>
<p>4. Purpose and scope of template SDO</p>	<p>4.1 To ensure the correct and controlled administration of Bicillin L-A for a patient who has had a diagnosis of ARF or has RHD and who is on secondary prophylaxis, by a person authorised according to the criteria in the template SDO.</p>
<p>5. Precautions</p>	<p>5.1 Do NOT inject into or near an artery or vein. Care must be taken with intramuscular administration of Bicillin L-A, to avoid intravenous or intra-arterial administration or injection in or near major blood vessels due to the risk of potential cardiorespiratory arrest and death.</p> <p>5.2 Do NOT inject into or near a nerve. Care must be taken with intramuscular</p>

Benzathine benzylpenicillin ~ TEMPLATE SDO

administration of Bicillin L-A, to avoid injection in or near major peripheral nerves due to the risk of neurovascular damage. Refer to sections 10.3, 10.4 and 11 for details regarding administration.

- 5.3** Administer slowly and closely monitor individuals with a history of significant allergies and/or asthma.
- 5.4** Administration of Bicillin L-A, is considered safe during pregnancy and lactation. Penicillin prophylaxis should continue for the duration of the pregnancy for prevention of recurrent ARF.
- 5.5** This template SDO is not applicable if the patient has had a previous injection with Bicillin L-A within the last 14 days.
- 5.6** Adrenaline must be readily available for treatment of an anaphylactic reaction.
- 5.7** **A history of a previous hypersensitivity reaction to any of the penicillins is a contraindication.**
- 5.8** **Do NOT** use short acting penicillin such as benzyl penicillin or procaine penicillin (Cilicaine®) injections for secondary prophylaxis in ARF patients. It does not provide long term protection.

6. Indications for use and dosage

Bicillin L-A is indicated as prophylaxis for ARF. Prophylaxis with Bicillin L-A has proven effective in preventing recurrence of this condition. It is also used as follow up prophylactic therapy for RHD. Duration of antibiotic prophylaxis for prevention of ARF recurrence depends on patient factors such as age, likelihood of ongoing exposure to GAS and time since last episode of ARF. Refer to the Guideline for more detailed information.

6.1 Bicillin L-A is recommended for:

- Persons with a history of ARF and/or RHD (refer to the Guideline for detailed information). Refer to Section 8 for contraindications.

6.2 Recommended schedule for intramuscular (IM) injection:

- 1,200,000 units / 2.3 mL as a single dose for persons ≥ 20 kg
- 600,000 units / 1.17 mL as a single dose for persons < 20 kg (refer to section 10 for part doses)
- One dose administered every 21 to 28 days. A dose every four weeks is recommended for most patients. Three weekly doses may be considered for:
 - patients with moderate or severe heart damage or a history of valve surgery who demonstrate good adherence to less frequent injections, and
 - patients who have confirmed breakthrough ARF, despite full adherence to 4-weekly Bicillin L-A.

***Children under 10 kg and under 12 months of age may require input from infectious disease regarding the correct dosing.

6.3 Recommended duration of secondary prophylaxis:

- Minimum five years after most recent episode of ARF or until aged 21 years (whichever is longer) and depending on symptoms at ARF diagnosis. Refer to the

Benzathine benzylpenicillin ~ TEMPLATE SDO

Guideline (www.rhdaustralia.org.au) for detailed information.

	Guideline (www.rhdaustralia.org.au) for detailed information.
7. Limitations	<p>7.1 This template SDO must only be applied to persons where it can be confirmed that they have been commenced on secondary prophylaxis with Bicillin L-A by a medical practitioner (refer to section 3.2).</p> <p>7.2 This template SDO does not replace a RHD management plan developed by a medical practitioner.</p>
8. Contra-indications and relative contraindications	<p>8.1 Previous hypersensitivity or anaphylactic reaction to any of the penicillins.</p> <p>8.2 Previous severe hypersensitivity to carbapenems and cephalosporin antibiotics.</p>
9. Presentation	<p>9.1 Bicillin L-A is presented as an injection, 1,200,000 units / 2.3 mL (viscous, opaque aqueous solution), prefilled syringe.</p> <p>9.2 Note: In 2019 the manufacturer Pfizer updated the labelling and packaging of benzathine benzylpenicillin to include the word tetrahydrate and describe the active ingredient in 'units' rather than 'mg'. There was no change to the contents of the product.</p>
10. Procedure	<p>10.1 Pre-administration</p> <p>10.1.1 Confirm that the patient is required to have Bicillin L-A as part of secondary prophylaxis for ARF and/ or ARF and has received a previous dose of Bicillin L-A. This is to be done as per section 3.2.</p> <p>10.1.2 Obtain consent from the patient (using the standard process operating in your health service)</p> <p>10.1.3 Ask the patient about any allergic reactions or hypersensitivity to penicillins, cephalosporins or carbapenem antibiotics. Ask the patient if there were any problems after previous Bicillin L-A injections. If there are any concerns about a possible allergic reaction refer to a medical practitioner.</p> <p>10.2 Equipment</p> <p>10.2.1 Equipment for <u>patients under 20 kg</u> in weight:</p> <ul style="list-style-type: none">• Pre-filled Bicillin L-A 1,200,000 units / 2.3 mL syringe• One 1 mL syringe• One drawing-up needle• 21G needle from the box of 10 Bicillin L-A• Medical sharps container <p>10.2.2 Equipment for <u>patients 20 kg and over</u> in weight:</p> <ul style="list-style-type: none">• Pre-filled Bicillin L-A 1,200,000 units / 2.3 mL syringe• One 1 mL syringe• One drawing up needle.• 21G needle from the box of 10 Bicillin L-A

- Medical sharps container

10.3 Preparation of Bicillin L-A

10.3.1 Check the batch number and expiry date with a second authorised person.

10.3.2 Inspect the Bicillin L-A syringe for any evidence of tampering and if present do not use.

10.3.3 Inspect for particles or discolouration and if present do not use.

10.4 Method of administration of Bicillin L-A

10.4.1 Warm Bicillin L-A syringe to body temperature.

10.4.2 Procedure for patients under 20 kg in weight:

- Attach a drawing up needle to a 1 mL syringe.
- Remove the screw cap from the pre-filled Bicillin L-A syringe.
- In presence of second authorised person, draw up very slowly 1.13 mL of Bicillin L-A from the pre-filled syringe into the 1 mL syringe, drawing up 1 mL first, discarding this into the dedicated sharps container, before drawing up 0.13 mL and discarding this with the 1 mL syringe and drawing up needle into the sharps container.
- Confirm dose with a second authorised person.
- Push plunger up carefully to remove any air in the Bicillin L-A syringe.
- Attach the intramuscular needle (21 gauge) provided in the Bicillin L-A box to the syringe to administer injection and prime to administer the injection.

10.4.4 Procedure for patients 20 kg and over in weight:

- Confirm dose with a second authorised person.
- Warm Bicillin L-A syringe to body temperature before using.
- Remove the screw cap from the pre-filled Bicillin L-A.
- Attach intramuscular needle (21 gauge) provided in the Bicillin L-A box to the syringe and prime to administer injection.

10.4.5 Landmark the appropriate site for injection. See section 11 for more details.

10.4.6 Apply pressure at injection site with thumb for 10 seconds before inserting needle.

10.4.7 Clean the proposed injection site with an alcohol swab and allow to dry.

10.4.8 Insert the needle at 90° to the skin, swiftly through the skin to minimise pain. After deep intramuscular insertion of the needle, draw back gently to make sure the tip is not in a blood vessel, and inspect the barrel for any blood or discolouration. If there is any discolouration, the needle must be withdrawn, and the syringe discarded.

10.4.9 Administer by deep intramuscular injection. Deliver injection very slowly; preferably over 2-3 minutes. Because of the high concentration of suspended material in Bicillin L-A the needle may be blocked if the injection is not made at a slow steady rate.

10.4.10 Discard the needle and syringe into a medical sharps container.

Benzathine benzylpenicillin ~ TEMPLATE SDO

<p>11. Site considerations</p>	<p>11.1 Administer by deep, intramuscular injection. It is recommended to use the ventrogluteal site (high lateral hip muscles - gluteus medius and minimus). In small children, the vastus lateralis site (anterolateral/outer middle thigh muscle) may be preferable.</p> <p>11.2 The dorso-gluteal site (upper outer quadrant of the buttock) is associated with risk of sciatic nerve injury, and this site must be used with caution.</p> <p>11.3 The deltoid muscle IS NOT recommended for Bicillin L-A administration due to large volume and viscosity.</p> <p>11.4 Use the opposite side than that used for the previous injection. The injection site should be rotated amongst appropriate sites for deep intramuscular injection for subsequent doses.</p>
<p>12. Documentation</p>	<p>12.1 Record in your patient information management system:</p> <p>12.1.1 Document how it was confirmed that the patient is on secondary prophylaxis.</p> <p>12.1.2 Valid consent obtained to administer injection.</p> <p>12.1.3 Bicillin L-A and lidocaine batch numbers, expiry dates, route and site of administration.</p> <p>12.1.4 Dose given (Bicillin L-A 1,200,000 units or 600,000 units)</p> <p>12.1.5 Date of administration.</p> <p>12.1.6 Name and organisation of the person administering; and</p> <p>12.1.7 Date the next injection is due (usually 28 days, or as per the patient's current management plan).</p> <p>12.2 Notify the patient's usual health service as soon as practicable.</p> <p>12.3 Report the injection to the RHD Register, where the information will be held securely; or add in the dose to the RHD Register if you have access to the RHD Register.</p> <p>This can be done by ensuring the dose is recorded on the RHD Master Chart, by phoning 08 7425 7146, faxing 08 7425 6697 or emailing rdh@sa.gov.au</p> <p>If the patient is not on the RHD Register and their usual residence is in South Australia, please notify the Register.</p>
<p>13. Monitoring requirements</p>	<p>13.1 Observation post-injection</p> <p>13.1.1 Adverse events including injection site reactions and anaphylaxis (see Section 15).</p> <p>13.1.2 After giving the injection, ask the patient to remain at the health service for at least 30 minutes.</p> <p>13.1.3 Adrenaline and directions for use must be routinely available for treatment of potential anaphylaxis.</p>
<p>14. Post injection advice</p>	<p>14.1 Post-injection advice</p> <p>14.1.1 Give verbal and written information about common adverse events. Refer to the Therapeutic Goods Administration website for full product information on Bicillin L-A https://www.tga.gov.au</p> <p>14.1.2 Ensure the patient knows when and where the next dose will be given and</p>

Benzathine benzylpenicillin ~ TEMPLATE SDO

document on card.

<p>15. Adverse events</p>	<p>Adverse events can include:</p> <p>15.1 Accidental intravascular administration Injection into an artery or vein may result in cardiorespiratory arrest and death. Accidental intravascular administration may also result in severe neurovascular damage with resultant damage to the limb.</p> <p>15.2 Hypersensitivity reactions Hypersensitivity reactions can be severe and may occasionally be fatal. The spectrum of reactions includes skin eruptions (maculopapular to exfoliative dermatitis), urticaria, laryngeal oedema, fever, eosinophilia, other serum sickness-like reactions (including chills, fever, oedema, arthralgia, and prostration) and anaphylactic/ anaphylactoid reaction (including shock and death). Fever and eosinophilia may frequently be the only reaction observed.</p> <p>Refer to the TGA website for full product information on Bicillin L-A https://www.tga.gov.au</p>
<p>16. Management of Adverse Drug Events (AE)</p>	<p>16.1 Monitor patient post injection for any adverse events. Manage an adverse event (such as anaphylaxis) or vasovagal episode (faint) as per your health service's current guidelines and contact a medical officer if required.</p> <p>16.2 Prompt consultation with an appropriate specialist is indicated if any evidence of compromise of the blood supply occurs at, proximal to, or distal to the site of injection.</p> <p>16.3 ALL suspected adverse drug events must be reported to the TGA. Report online at the TGA website www.tga.gov.au by following the link to 'Report a problem'.</p>
<p>17. Storage</p>	<p>17.1 Store between +2°C and +8°C. Do not freeze.</p>

STAFF PROVIDING THE SERVICE

I have read and understand the recommendations of the Standing Drug Order. I accept that I will administer this injection under the described procedure in this Standing Drug Order.

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

Signature: _____ Printed name: _____ Date: _____

APPENDIX A

Reference: 2020 guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (3rd edition). Detail on the strategies below is provided in the Guideline, available from www.rhdaustralia.org.au

Non-pharmacological pain minimisation strategies

- a patient-focussed, culturally safe environment
- respect for the patient's preference for pharmacological pain management strategies and site for injection (within the guidelines for appropriate delivery site)
- relationship-based and relationship strengthening activities such as use of incentives and rewards
- family or support person involvement during injection procedures
- minimal waiting time for injection
- best practice injection technique
- allowing skin swabbed with alcohol to dry before injecting
- distraction during injection with electronic games, videos etc
- injecting slowly
- firm pressure to the site for at least 10 seconds immediately before injecting.
- ice pack applied to the site before injecting
- use of ice or vibration device (e.g., Buzzy®, a vibrating ice pack) applied directly adjacent to the injection site during injection
- use of other devices to provide distracting stimuli to the skin (e.g., Shot Blocker, a piece of plastic shaped to fit around and above the injection site and pressed to the skin with multiple, small, blunt bumps to 'saturate sensory nerves')
- refrigerating the needle prior to injection delivery.

Pharmacological pain minimisation strategies: analgesia and sedation

- oral paracetamol approximately 30 minutes before injection and at appropriate time intervals afterwards as required
- anaesthetic cream at least 20 minutes before injection or spray onto the injection site before injection
- lidocaine injected with BPG or Bicillin L-A
- nitrous oxide (Entonox) during the injection procedure
- oral clonidine prior to injection (for children and adolescents who are highly distressed with the injections despite use of other strategies).

Clinical scope of practice, local protocols and policies, and supply of medications and medical gases must be considered when using any of these pharmacological strategies.