SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Pentamidine Aerosolised Therapy in Adults
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/696
DATE OF PUBLICATION	June 2022
RISK RATING	Medium
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 4 - Medication Safety
REVIEW DATE	June 2025
FORMER REFERENCE(S)	POWH Clinical Business Rule - POWH CLIN042 Pentamidine Aerosolised Therapy in Adults
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Clinical Stream Director, Medicine
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FUNCTIONAL GROUP(S)	Cardiac and Respiratory Care
KEY TERMS	Pentamidine Pneumocystis jiroveci Pneumonia (PJP)
SUMMARY	Procedure to guide clinicians with the administration of pentamidine aerosolised therapy.

Pentamidine Aerosolised Therapy in Adults SESLHDPR/696

1. POLICY STATEMENT

The purpose of this procedure is to provide clinical guidance and a framework to ensure the safe administration of aerosolised Pentamidine in the prevention and treatment of Pneumocystis Jiroveci Pneumonia (PJP) in patients unable to tolerate co-trimoxazole (Trimethoprim with sulfamethoxazole).

- Prior to nebulised Pentamidine, all alternative options must be considered such as Dapsone with Trimethoprim or other oral agents.
- Prescription and administration of nebulised Pentamidine needs approval via consultation with Infectious Diseases.
- Pentamidine nebulisation must be administered in a negative pressure room.

The procedure shall be read in conjunction with the following Ministry of Health policy directives:

- Medication Handling in NSW Public Health Facilities PD2013_043
- Infection Prevention and Control Policy PD2017_013

COVID considerations

- Comply with current local COVID risk assessment requirements.

2. BACKGROUND

Aerosolised Pentamidine therapy is predominately administered as prophylactic therapy for the prevention of *Pneumocystis jiroveci* Pneumonia (PJP) in patients who are unable to tolerate co-trimoxazole (Trimethoprim with sulfamethoxazole).

PJP is a life-threatening lung disease caused by an organism *Pneumocystis jiroveci*. This organism can also infect and cause disease in other organs, including the skin (extra pulmonary *Pneumocystis* infection). *Pneumocystis jiroveci* is transmitted by aerosol from infected individuals.

3. RESPONSIBILITIES

All SESLHD staff providing Pentamidine aerosolised therapy will act in accordance with this procedure:

- Managers: ensure dissemination and implementation of the procedure to relevant clinicians within their facility/department; ensure that clinical staff administering aerosolised pentamidine have access to appropriate equipment, including personal protective equipment (PPE) and consumables to ensure safe administration; ensure staff administering Pentamidine aerosolised therapy have access to appropriate training; ensure administration occurs in a negative pressure room
- Medical Staff: complete any education/training in relation to the safe administration to ensure knowledge and practical skill
- Nursing staff: complete any education/training in relation to the safe administration to ensure knowledge and practical skill
- Pharmacists: Advise of potential drug interactions.

4. DEFINITIONS

PJ	Pneumocystis jiroveci
PJP	Pneumocystis jiroveci Pneumonia
FEV1	Forced expiratory volume

5. COMPETENCY/ASSESSMENT

All registered and enrolled nurses must successfully complete the medication assessment requirements in accordance with any facility Medication Management Clinical Business Rules

All staff entering the negative pressure room during the administration of pentamidine aerosolised therapy must be competent in the fitting and removing of personal protective equipment including N95 or P2 masks.

Knowledge / skills to perform spirometry and evaluate results.

6. PROCEDURE

Indication

Prophylaxis for PJP infection, where the person is hypersensitive or unresponsive to co-trimoxazole[3,6]

Prescription

- Consider all alternative options such as Dapsone with Trimethoprim or other oral agents prior to nebulised Pentamidine prescription
- Gain approval via consultation with Infectious Diseases

Dosage and administration guidelines[4]

Drug description	Dose
Pentamidine Isethionate for injection A white or almost white, odourless or almost odourless hygroscopic power. Each 4mg of Pentamidine isethionate is equivalent to 2.3 mg pentamidine base.	**Adult:** Pentamidine Isethionate 300mg diluted in 6mL sterile water, and nebulised once per month.* *Or as prescribed in consultation with Infectious Diseases.

Drug Interactions

- Check for drug interactions via MIMS or with pharmacist prior to administration. https://www.mimsonline.com.au.acs.hcn.com.au/Search/Search.aspx

Contraindications[3,6]

- People with a known hypersensitivity to Pentamidine
- Pentamidine should not be administered to women who are pregnant or breastfeeding unless considered essential

Precautions[3.6]

Environment

Pentamidine nebulisation must be administered in a negative pressure room with a viewing window for visual observations of the patient.

Minimising Bronchoconstriction

Due to propensity to cause bronchoconstriction conduct spirometry pre and post treatment Consider additional salbutamol if there are significant changes.

- Pre-treatment: Consider whether pre-treatment salbutamol is required. See Pre-existing Conditions below.
- Post treatment: Administer additional salbutamol if there is a drop from the pre-treatment spirometry. **A 12% drop or more in FEV1 from base line would indicate need for salbutamol.**

Pre-existing Conditions

- Because side effects include bronchospasm or cough, patients who are smokers or those with a history of asthma or reactive airway disease may benefit from pre-treatment with a bronchodilator.
- Patients with severe asthma or a history of extensive smoking may not tolerate pentamidine inhalation therapy.
- Pentamidine inhalation should be used with caution in patients with hypoglycaemia, hyperglycaemia or glucose intolerance, diabetes mellitus, thrombocytopenia, asthma, or hepatic, renal, or pulmonary dysfunction; some authorities state that the drug should not be used in patients with a history of hypoglycaemia, pancreatitis, arrhythmia, or severe hypotension associated with administration of pentamidine by any route.

For Staff

- Pregnant health care workers should not administer aerosolised pentamidine. Other health care workers attempting to conceive should also avoid exposure.
- It is essential to minimise exposure to aerosolised pentamidine to staff and others due to the recognised side effects such as eye and respiratory irritation.
- As inhaled pentamidine is an aerosol generating procedure, patients undergoing this procedure must be risk assessed for potential COVID-19. This may include patient assessment using the COVID-19 screening tool.
- In addition, staff members administering inhaled pentamidine must adhere to ‘Contact + Droplet + Airborne Precautions in addition to Standard Precautions’ regardless of the patient not fulfilling COVID-19 isolation or testing criteria.
- Inhaled pentamidine must not be administered in patients that satisfy COVID-19 isolation or testing criteria. Such instances must be discussed with the patient’s

medical consultant for consideration of COVID-19 testing and deferment of the procedure or alternative therapies.

Adverse effects[4]

- Pentamidine inhalation commonly causes cough and bronchospasm. It is much less toxic than Intravenous (IV) pentamidine
- Adverse effects by inhalation include cough and bronchospasm (reduced by using a bronchodilator first), nausea, vomiting, diarrhoea, taste disturbance, hyper salivation, eye discomfort, fatigue, rash, toxic epidermal necrolysis, eosinophilic pneumonia, raised liver enzymes, hypoglycaemia, pancreatitis.
  Adverse effects include: dizziness, tachycardia, palpitations, chest pain, syncope, confusion, oxygen desaturation

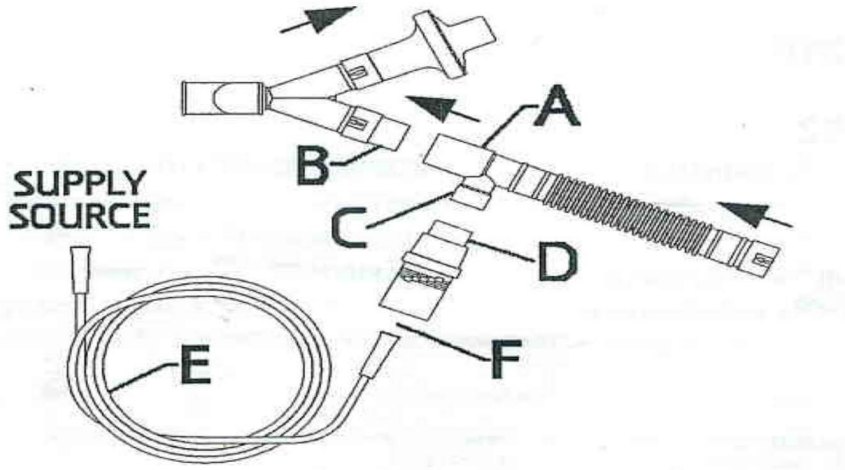
Equipment

- Aerosol delivery system e.g. Respirgard-II Nebulizer with filter. Single use only; Discard after use.
- High flow nebuliser pump with 8-10 litre/minute output or air cylinder at 8-10 litre/minute flow.
- Spirometer
- Pentamidine isethionate
- 6 mL sterile water for Injection
- 10 mL syringe, and drawing up needle
- A bronchodilator if indicated as directed by the prescriber
- N95/P2 face-masks, mask fit tested individually to the administering staff member.
- Eye protection such as goggles
- Face shields
- Gowns or aprons, as deemed appropriate as per staff member risk assessment.

Preparation

- Assemble Respirgard-II Nebulizer system as per manufacturer's instructions
- Inject 6mL of sterile water into pentamidine isethionate vial (300 mg), and dissolve by shaking vigorously.
- Draw up solution into syringe, and place in nebuliser

Respirgard-II Nebulizer: Product Information



Patient Monitoring

- Vital signs should be recorded pre and post procedure.
- As Pentamidine can cause bronchospasm conduct spirometry prior to pentamidine administration. Assess patient's history for the need of a bronchodilator pre-treatment.
- During treatment monitor for potential adverse effects.
    - If serious adverse effects are identified cease pentamidine nebuliser and contact treating team for review. Escalate in line with Between the Flags parameters.
    - Report adverse drug reaction in accordance with facility Medication Management Business Rules
- Conduct spirometry post drug administration
    - Administer additional salbutamol if there is a drop of **12% or more in FEV1 from base line/pre-treatment spirometry.**

Administration (NB Administer in a negative pressure room).

- Provide explanation to patient/carer
- To optimise administration effectiveness, the patient should be in upright position. Refer to prescribing MO if unable to tolerate upright position. For patients requiring pre-treatment with bronchodilator, administer prior to commencement of administration of pentamidine.
- Instruct the patient to seal the lips around the mouthpiece and inhale and exhale through the mouth. The patient should breathe normally and take a slow deep breath with a 2 second hold every 10 breaths. If patients tend to breathe through the nose, a nose clip should be applied.
- Patient must be closely monitored and observed. Check patient intermittently for side effects of pentamidine:
    a) Bronchospasm – stop nebuliser and seek urgent MO review / escalate via BTF
    b) Excessive cough – ensure air flow rate <10L/min, reduce inspiration rate

- If it is necessary for staff to enter the room during the procedure, they must wear a protective face mask (P2) and appropriate PPE as per 'Contact + Droplet + Airborne Precautions, donning and doffing competently and donning new PPE when required.
- If necessary, the patient may take a short break during the procedure, at which time the air supply to the nebuliser should be turned off before the circuit is removed from mouth.
- Aerosolise until the nebuliser runs dry. Length of time for administration is 30 to 45 minutes.

Post Treatment / Room Cleaning

- When entering the room post patient discharge, airborne precautions must be adhered to as dictated by the number of air changes per hour (ACH), available in the Clinical Excellence Commission Infection prevention and control practice handbook.
- The room must be terminally cleaned and shared equipment e.g. blood pressure machines, disinfected.

Ongoing Treatment

- Treatments are usually monthly and in consultation with the Infectious Diseases team.
- 300mg nebulised/monthly or otherwise prescribed by medical staff.
- For patient with human immunodeficiency virus (HIV) infection treatment may be ceased when CD4 count is consistently >200 cells/µL.

7. COMPLIANCE EVALUATION

All inpatients receiving Pentamidine will have approval in accordance with SESLHD Antibiotic List with restrictions.

8. DOCUMENTATION

Document all activity relating to a patient's appointment or attendance or non-attendance and consequent actions of clinical staff in the patient's health care record.

9. AUDIT

Not required.

10. REFERENCES

Number	Reference
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10.	SESLHDPD/137- Antimicrobial Stewardship. September 2014.
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10. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
December 2020	Draft	Request to convert POW Clinical Business Rule to district document. SESLHD Procedure drafted.
November 2021	Draft	Approved by Executive Sponsor, Clinical Stream Director, Cardiac and Respiratory. Tabled at SESLHD Quality Use of Medicines Committee.
December 2021	Draft	To be tabled at Antimicrobial Stewardship Clinical Application Advisory Group for approval.
April 2022	Draft	Approved at the Quality Use of Medicines Committee. Approved by Clinical and Quality Council.
June 2022	1	Processed and published by SESLHD Policy