SESLHD PROCEDURE COVER SHEET



NAME OF DOCUMENT	Pentamidine Aerosolised Therapy in Adults
TYPE OF DOCUMENT	Procedure
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LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 4 - Medication Safety
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FORMER REFERENCE(S)	POWH Clinical Business Rule - POWH CLIN042 Pentamidine Aerosolised Therapy in Adults
EXECUTIVE 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.



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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:

- PD2022_032 Medication Handling
- PD2023 025 Infection Prevention and Control in Healthcare settings

COVID-19 considerations:

Comply with current local COVID-19 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
- <u>Medical Staff</u>: complete any education/training in relation to the safe administration to ensure knowledge and practical skill

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- <u>Nursing staff:</u> 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 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 cotrimoxazole^{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 guidelines⁴

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

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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 <u>must</u> 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 Preexisting Conditions below.
- Post treatment: Administer additional salbutamol if there is a drop from the pretreatment 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 pretreatment 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, asthma, pancreatitis, hepatic, renal, or pulmonary dysfunction.

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 Acute Respiratory Infection.
- If a patient has signs/symptoms of an Acute Respiratory Infection, 'Contact, Droplet and Airborne' transmission-based precautions must be used.
- If a patient does NOT have signs/symptoms of an Acute Respiratory Infection 'Airborne' precautions must be utilised given the recognised side effects of eye and respiratory irritation.

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 For further information about PPE and standard and transmission based precautions refer to the NSW Health NSW Health PD2023 025 - Infection Prevention and Control in Healthcare Settings and SESLHDPR/581 - Management of Acute Viral Respiratory Illness (including influenza and COVID-19)

Adverse effects4

- 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

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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 <u>Clinical Excellence Commission Infection prevention and control practice handbook</u>.
- The room must be terminally cleaned and shared equipment e.g. blood pressure machines, disinfected.

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COMPLIANCE WITH THIS DOCUMENT IS MANDATORY





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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 SESLDHPD/137-Antimicrobial Stewardship

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

IMS+ review. Pharmacy to monitor compliance and usage.

10. REFERENCES

Number	Reference	
1.	NSW Health NSW Health PD2023 025 Infection Prevention and Control in Healthcare Settings and SESLHDPR/581 Management of Acute Viral Respiratory Illness (including influenza and COVID-19)	
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4.	Pentamidine. Australian Medicines Handbook. 2025. https://amhonline.amh.net.au.acs.hcn.com.au/chapters/antifungals/other-antifungals/pentamidine?menu=hints	
6.	Guidelines for Prevention and Treatment of Opportunistic Infections in HIV- Infected Adults and Adolescents. Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Morbidity and Mortality Weekly Report. 2009 April 10 vol 58.	

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8.	DBL. Pentamidine Isethionate for Injection. Product information. June 2022.
9.	SESLHDPR/267 - Medication Management. /November 2024
10.	SESLHDPD/137- Antimicrobial Stewardship. October 2024
11	Clinical Excellence Commission, 2020, Infection prevention and control practice handbook. Clinical Excellence Commission, Sydney, Australia.

11. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
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
10 July 2025	1.1	Minor review: references and links updated; terminology updated from competency to training; COVID-19 information updated; pre existing conditions reviewed and revised; audit requirements updated. Approved at July SESLHD Drug and Therapeutics Committee.

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