1.0 DESCRIPTION

1.1 Definition: Pentamidine isethionate is an anti-microbial agent effective in the treatment of *Pneumocystis carinii* pneumonia. Prophylactic aerosolization of this agent has been shown to be effective in reducing the number of *P. carinii* infections in HIV-infected individuals. The Centers for Disease Control and Prevention have recommended that patients with the human immunodeficiency virus (HIV) whose CD4+ lymphocyte counts have fallen to 200/mm$^3$ or fewer receive prophylaxis against *P. carinii*. Other immunocompromised patients may benefit from prophylaxis, or occasionally, patients with *P. carinii* who are intolerant to other antimicrobials may receive aerosolized treatments, although this is not considered first-line treatment.

Pentamidine is administered via the Respirgard II nebulizer which utilizes a series of one-way valves and a filter to minimize the release of aerosol droplets into the air. Aerosolized pentamidine may be potentially toxic (see 1.4 Precautions and 1.5 Adverse Reactions and Interventions) necessitating this special nebulization system. The standard dose is 300 mg of lyophilized pentamidine isethionate dissolved in six ml of sterile water and aerosolized until the nebulizer runs dry. This therapy is generally given on a monthly basis.

1.2 Indications

1.2.1 HIV-positive patients whose CD4+ count is at or below 200/mm$^3$ or have a history of *P. carinii* pneumonia

1.2.2 HIV-positive patients who are intolerant to other anti-*Pneumocystis* chemoprophylactic or therapeutic agents

1.2.3 Other immunocompromised patients for whom pentamidine prophylaxis is deemed beneficial (i.e. oncology patients with
primary immunodeficiencies of those receiving chemotherapy with secondary immunodeficiencies, bone marrow transplant patients, and patients receiving prolonged administration of high-dose steroids.)

1.3 Contraindication: Pentamidine prophylaxis is contraindicated in patients with demonstrated hypersensitivity to inhaled or parenteral pentamidine.

1.4 Precautions

1.4.1 Because there is considerable potential for acute side effects from the inhalation of pentamidine, it is imperative that the respiratory therapist be in attendance with the patient at all times during therapy. Potential side effects include fatigue, metallic taste, drooling, shortness of breath, dizziness, nausea, pharyngitis, chest pain, pneumothorax, tachycardia, palpitations, syncope, hypertension, gingivitis, dry mouth, confusion, anxiety, seizure, laryngospasm, conjunctivitis, and blurred vision.

1.4.2 Other potential side effects of pentamidine inhalation include bronchospasm and cough. Especially in patients with asthma or reactive airways disease, pre-treating with a bronchodilator may be beneficial. For patients who have documented or suspected airway reactivity to the therapy, a bronchodilator must be administered prior to pentamidine prophylaxis.

1.4.3 Side effects for bystanders and for health care workers administering pentamidine therapy include shortness of breath, headache, burning of the eyes, nose, and throat, nausea, and lightheadedness.

1.4.4 To minimize the risk of exposure for others outside of the room to aerosolized particles of pentamidine, pentamidine prophylaxis should be performed in negative flow isolation rooms and/or a laminar flow hood.

1.4.5 Flow to the nebulizer should be terminated prior to removal of the nebulizer from the patient's mouth.

☆ 1.4.6 Because pentamidine inhalation may be cough-provoking, treatments for patients potentially infectious for *Mycobacterium tuberculosis* must be done in negative flow rooms, and all precautions for minimizing the risk of tuberculosis transmission must be followed. See Clinical Center Policy #M93-8 "Use of Disposable Particulate Respirator Masks to Reduce Airborne Transmission of Infectious Organisms in the Clinical Center" and
The National Institutes of Health Respiratory Protection Program for further Information. ★

1.4.7 The risks of pentamidine exposure for pregnant women, their unborn babies, and nursing mothers, and the effects on fertility are unknown. All decisions to administer pentamidine aerosol therapy to pregnant or nursing women must be weighed against these unknown risks. Pregnant health care workers are not permitted to administer aerosolized pentamidine; other health care workers attempting to conceive should avoid exposure (see the CCMD Work Policy for Pregnant Employees).

1.4.8 Patients on oxygen therapy and pediatric patients require pulse oximetry monitoring during therapy.

1.4.9 Pediatric patients require a pre-treatment nursing assessment.

1.4.10 Some patients may require the use of noseclips in order to create the negative pressure required to breathe through the one-way valves.

1.5 Adverse Reactions and Interventions

1.5.1 If bronchospasm ensues during or after pentamidine therapy, secure an order from the physician to administer a bronchodilator. Patients with a history of airway reactivity to aerosolized pentamidine should be pre-treated with a bronchodilator.

1.5.2 Rest periods should be allowed due to fatigue resulting from breathing through the one-way valves and maintaining a tight lipseal on the mouthpiece.

1.5.3 The patient may complain of a burning sensation in the back of the throat usually occurring in the latter part of therapy. This is usually resolved by temporarily discontinuing therapy and allowing the patient to have a drink of some liquid (avoid orange juice).

1.5.4 Notify the physician or nurse practitioner if any of the more serious complications (i.e. chest pain, palpitations, syncope, confusion, seizure, marked desaturation, etc.) occur during therapy and document in the patient's chart.

1.5.5 The pre-filter on the laminar flow hood must be changed once per month.
1.5.6 Decontamination of the laminar flow hood should be scheduled every 6 months. Call the Safety Department (at 6-3457) to arrange for decontamination.

2.0 SCHEDULING APPOINTMENTS

2.1 All aerosol pentamidine therapies require pre-scheduled appointments. Appointments are usually scheduled every two to four weeks.

2.2 Treatments are scheduled in Meeting Maker in 1 hour increments. This allows for travel time in the Clinical Center for the patient and family.

2.3 Patients who are on Respiratory/Strict Isolation will not receive therapy until these restrictions have been resolved.

2.4 The Pentamidine Lab's voice mail must be checked at least three times a day by the therapist covering the lab, in order to accommodate scheduling needs or changes.

3.0 ORDERING MEDICATION

3.1 All ordering physicians/nurse practitioners are to place in the MIS system standard orders for pentamidine and a bronchodilator.

3.2 A standard PRN bronchodilator order should be ordered with each pentamidine therapy.

3.3 A nebulizer with .5cc Albuterol/NSS to be administered pre/post pentamidine therapy.

3.4 All patients are required to have current orders for pentamidine medication. (i.e. 300mg Pentamidine to be administered in clinic on __/__/00).

4.0 EQUIPMENT AND MATERIALS

4.1 Oxygen flowmeter with nipple adapter

4.2 Respirgard II nebulizer system

4.3 Lyophilized pentamidine isethionate (300mg)

4.4 One ten ml vial of sterile water for injection

4.5 10 ml syringe with 18 gauge needle

4.6 Universal precautions attire
4.7 Particulate respirator masks

4.8 Negative flow room

4.9 Small volume nebulizer and bronchodilator or metered dose inhaler (as needed)

4.10 Pulse oximeter: required for pediatric patients and those on oxygen

4.11 Facial tissue

4.12 Emesis basin

4.13 Liquid drink (as needed)

4.14 Noseclips (as needed)

NOTE: Supplies must be checked every day.

5.0 PROCEDURE

5.1 Preparation of the aerosol solution:

5.1.1 Obtain the vial of 300 mg of lyophilized pentamidine isethionate.

5.1.2 Don gloves and instill 6 ml of sterile water into the vial and agitate the vial until a homogenous solution (free of clumps) results.

5.1.3 Assemble the Respirgard II nebulizer and place the pentamidine solution into the nebulizer.

5.1.4 All patients will be placed in front of laminar flow hood while receiving aerosolized pentamidine therapy while in the Pentamidine Lab.

5.1.5 Perform a pre-treatment assessment to include breathing pattern and frequency, heart rate, breath sounds, SpO₂ (as appropriate) and determine cognitive ability. In case of a pediatric patient, nursing must be notified so an additional nursing assessment may be performed.

5.1.6 Administer a bronchodilator (if necessary).

5.1.7 Explain the treatment procedure thoroughly to the patient and to the parent or guardian (as appropriate).
5.1.8 Don universal precautions attire and a particulate respirator mask. Parents/guardians and others remaining in the room during therapy must also wear a particulate respirator mask.

5.1.9 Assist and coach the patient as needed to achieve complete aerosolization of the solution volume at a liter flow of 6 liters per minute. Instruct the patient to breathe normally and to inhale and exhale through his/her mouth. Treatment time varies between 20 and 45 minutes.

5.1.10 Reassess the patient intermittently during the treatment and at the conclusion of therapy.

6.0 POST PROCEDURE

6.1 Discard the nebulizer and other disposable items.

6.2 A follow-up call must be made to all new patient's MD/RN with a report of the patient's tolerance to treatment.

6.3 If a patient fails to keep a scheduled appointment, a call must be placed to the contact person listed on his or her treatment record.

6.4 Wipe down inside of hood and desk with disinfectant, then with glass cleaner. Complete the cleaning process by using glass cleaner.

7.0 DOCUMENTATION

Document the treatment in the MIS system. Documentation pathway for charting Pentamidine treatment can be found under “Aerosol Therapy” in the “Patient Treatment Record” pathway. Include the following into your documentation:

- 7.1 drug
- 7.2 dosage and duration
- 7.3 laminar flow pressure
- 7.4 assessment
- 7.5 tolerance

Note any adverse reactions and/or if the patient required pre-treatment or treatment with a bronchodilator. Note also any special procedural modifications required.

8.0 GENERAL INFORMATION

8.1 Pentamidine Lab Location - 7W263

8.2 Operation Hours - 7AM-4PM, M-Th.
8.3 Telephone Number - 301-402-3713
8.4 Pager - 104-3702-7

9.0 REFERENCES


9.2 Physician's Desk Reference.


9.4 CCTRCS Pediatric Aerosolized Pentamidine Administration Policy.

9.5 Critical Care/Heart, Lung, Blood/ Neuro Nursing Service Procedure: Pediatric Patients Receiving Aerosolized Pentamidine Administration.

9.6 Clinical Center Policy #M93-8 "Use of Disposable Particulate Respirator Masks to Reduce Airborne Transmission of Infectious Organisms in the Clinical Center."

9.7 The National Institutes of Health Respiratory Protection Program.

9.8 CCMD Work Policy for Pregnant Employees.
SIGNATURE: ____________________________ DATE: __________
Assistant Section Chief, CCTRCS, CCMD

SIGNATURE: ____________________________ DATE: __________
Section Chief, CCTRCS, CCMD

SIGNATURE: ____________________________ DATE: __________
Medical Director, CCTRCS, CCMD

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