وزارة الصحة
Ministry of Health

Dispensing Respiratory Equipment Protocol

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Scope

This protocol outlines the procedures for dispensing respiratory equipment at Ministry of Health hospitals, including the indications for use and the identification of authorized personnel responsible for dispensing

Definitions

a. Oxygen devices:

Medical apparatus designed to deliver supplemental oxygen to individuals with low blood oxygen levels (hypoxemia) resulting from various medical conditions. These devices are used to enhance the patient's oxygen intake, improve oxygen saturation in the blood, and support respiratory function.

I. **Oxygen concentrator**

It is a medical device that provides supplemental oxygen to individuals with respiratory conditions that impair their ability to breathe or maintain adequate oxygen levels. It works by extracting oxygen from ambient air and delivering it to the patient at a specified concentration and flow rate.

There are two types of oxygen concentrators

- **Stationary Oxygen Concentrators:** Larger units meant for home use that provide continuous oxygen flow, typically connected directly to a power supply.
- **Portable Oxygen Concentrators:** These concentrators are more expensive and designed for mobility. These units are smaller, lighter, and can be powered by batteries or external power sources, making them suitable for use during travel.

ii. **Oxygen Cylinders (Oxygen Tanks)**
Pressurized gas cylinders of different sizes that store and supply oxygen for use, often used in hospitals or in emergencies, and can be portable for use outside the home.

b. Continuous Positive Airway Pressure (CPAP)

It is a medical treatment that delivers a constant flow of air through a device to maintain open airways in individuals who have breathing difficulties, particularly during sleep or during respiratory failure

c. Bilevel Positive Airway Pressure (BiPAP)

It is a non-invasive mechanical ventilation therapy that provides two levels of airway pressure to assist patients with breathing difficulties. Unlike Continuous Positive Airway Pressure (CPAP), which delivers a single constant pressure, BiPAP has two distinct pressure settings.

Definitions		
Device	**Function**	**Key Features**
Stationary Oxygen Concentrator	Provides continuous oxygen flow for home use	Larger unit; connects to mains power; long-term therapy
Portable Oxygen Concentrator	Delivers supplemental oxygen with mobility	Small, lightweight; battery or external power; suitable for travel
Oxygen Cylinder (Tank)	Stores and supplies pressurised oxygen gas	Various sizes; used in hospitals, emergencies, and portable situations
Continuous Positive Airway Pressure (CPAP)	Delivers a constant flow of air to maintain open airways	Single constant pressure; used for sleep apnoea and respiratory failure
Bilevel Positive Airway Pressure (BiPAP)	Provides two levels of airway pressure for breathing assistance	Distinct inspiratory and expiratory pressures; non-invasive

Clinical Indications for Home Oxygen Therapy Equipment

a. dispensing oxygen therapy devices

General criteria

1. Oxygen devices must meet safety and performance standards set by relevant healthcare authorities.
2. The prescribing physicians must
   2.1. Have conducted a thorough and recent evaluation of the patient and determined that the use of the prescribed home oxygen is medically necessary for the patient's condition

2.2. Be a board-certified pulmonologists (can prescribe all types of oxygen therapy devices).
2.3. Be a board-certified internists/ paediatrician (can prescribe oxygen cylinder devices only).

3. The medical assessment of the patient's needs for oxygen therapy devices and the prescription of these devices must both be made by the same physician and must not be more than 30 days apart for long-term indications and no more than 7 days apart for short-term indications.
4. Patient Education: Patients should receive comprehensive education on:
   4.1. Proper use, maintenance, and troubleshooting of the oxygen concentrator.
   4.2. Safety precautions, including fire safety and oxygen handling protocols. Recognizing signs of inadequate oxygenation or complications.

B. **Specific Coverage Criteria for Stationary Home Oxygen Concentrators**

I. The prescription of oxygen therapy devices must be signed and dated by the prescribing physician and include **ALL** of the following information:
- Oxygen flow rate.
- Frequency and duration of use.
- An estimate of the period of need.
- The results of a current blood gas analysis report were obtained at rest and at room air (performed no more than 14 days before the prescription). However, oxygen saturation may be determined by pulse oximetry when ABGs cannot be taken.
- Listing of all external (out-of-package) appliances that are necessary for the proper use of the device (e.g. special masks, air humidifiers, etc.)
- Target oxygen saturation

II. The following diagnostic findings support the need for oxygen therapy for both short-term and long-term indications:

1. For adults, Laboratory results of oximetry or arterial blood gases must show:

i. A current ABG with a PaO2 persistently ≤ 55 mm Hg on two or more separate occasions (at least one week apart), or SaO2 ≤ 88 % on two or more separate occasions (at least one week apart), taken at rest, while breathing room air. OR

ii. Oxygen desaturation of ≤ 88% on exertion with significant symptoms on two or more separate occasions (at least one week apart). OR

iii. PaO2 at 56-59 mm Hg or SaO2 ≤ 89 % with chronic polycythaemia (haematocrits > 55%) or with evidence of pulmonary hypertension (based on physical exam findings PLUS ECG criteria (appendix 1) or based on echocardiography criteria mean Pulmonary Artery Pressure PAP≥ 25).

2. **For children, Laboratory results of oximetry or arterial blood gases must show:**

i. A current ABG with a PaO2 persistently ≤ 65 mm Hg on two or more separate occasions (at least one week apart), OR SaO2 ≤ 90 % on two or more separate occasions (at least one week apart), taken at rest, while breathing room air. OR

ii. Oxygen desaturation of ≤ 90% on exertion with significant symptoms on two or more separate occasions (at least one week apart).

III. Despite intensive medical evaluation and management by the medical team, the patient continues to have either:

i. An irreversible respiratory condition resulting in a persistent, hypoxemic respiratory state requiring continued, at-home oxygen therapy. OR

ii. A respiratory condition in which chronic, at-home oxygen treatment has a clear mortality or morbidity benefit.

IV. The medical indications for prescribing oxygen therapy devices should fall into one <u>of two categories as follows</u>:

A. **Short-term indications (estimated need is less than 6 weeks):** all the following criteria must be met:

I. The evaluation and prescription of oxygen therapy devices are carried out by a board-certified pulmonologist or a board-certified internist.

II. The patient is hospitalized or has been recently discharged with a recent acute or subacute persistent hypoxemic respiratory state and either:

a. The hypoxemic respiratory state could not be reversed despite intensive medical management during hospitalization

by a medical team that included a board-certified pulmonologist or a board-certified internist.

OR

b. The hypoxemic respiratory state could be reversed but is expected to require a prolonged time (more than 2-6 weeks) to improve despite intensive medical management during hospitalization by a medical team that includes a board-certified pulmonologist or a board-certified internist.

c. The treating physician or designated healthcare provider must evaluate the patient's condition and the necessity for long-term oxygen therapy 3 months post-discharge. If the oxygen saturation is ≥92% while breathing room air, the oxygen therapy will be discontinued, and the oxygen concentrator must be returned to the hospital.

B. **Long-term indications (estimated need is > 6 weeks): all the following criteria must be met:**

I. Evaluation and prescription of the oxygen therapy devices is made by a board-certified pulmonologist.

II. The patient must have been diagnosed by a board-certified pulmonologist to have a chronic, persistent, irreversible chest condition and that he is in a stage that requires a chronic, at-home oxygen therapy device for therapeutic or symptomatic benefits. Examples of these conditions are:

a. Chronic obstructive pulmonary disease (COPD), advanced bronchiectasis; advanced interstitial lung diseases, advanced primary or secondary pulmonary hypertension; advanced heart failure; severe symptomatic, restrictive chest wall diseases; advanced lung cancer; refractory severe symptomatic pleural effusions; severe bronchopulmonary dysplasia (BPD); severe cystic fibrosis; severe congenital or developmental pulmonary diseases; severe tracheomalacia; palliative care patients who are hypoxemic or have persistent dyspnea that are only relieved by supplemental oxygen, patients who are undergoing pulmonary rehabilitation program at home and require supplemental oxygen for improving their functional capacity.

b. Other diagnoses based on a documented medical necessity indicated by a board-certified pulmonologist.

III. Clear documentation that the treating medical team has ruled out the possibility that the patient's persistent need for oxygen is not related to a reversible, comorbid medical illness.

The prescription of a portable oxygen concentrator must fulfil ALL of the following criteria:

A. **Patient is mobile, physically active, and regularly goes outside the home**:
Patient, as assessed by treating physician, requires supplemental portable oxygen for daily activities outside the home and will benefit from increased mobility and independence. **And**

B. **Meet the Oxygen therapy dispensing indication criteria AND**

C. **ALL the following criteria:**

I. The prescribing physicians must have conducted a thorough and recent evaluation of the patient and determined that the use of the prescribed home oxygen is medically necessary for the patient's condition.

II. The medical assessment of the patient's needs for oxygen therapy devices and the prescription of these devices must both be made by the same physician and must not be more than 30 days apart for long-term indications and no more than 7 days apart for short-term indications

III. The prescribing physician must be a board-certified specialist physician as follows:

a. Board-certified pulmonologists.

Specific coverage criteria for prescribing Oxygen Cylinders:

A. Clinical Indications for Oxygen Cylinder Prescription

Oxygen cylinders may be prescribed for short periods for patients requiring supplemental oxygen therapy temporarily, with the expectation that their acute medical condition is reversible. Examples of these reversible medical conditions, including but not limited to:

- Exacerbation of COPD
- asthma exacerbations
- Pneumonia or other pulmonary infections
- Congestive heart failure with hypoxemia

- Any condition resulting in chronic hypoxemia as demonstrated by arterial blood gas analysis or pulse oximetry.

Authorized Prescribers:

Only the following healthcare professionals are authorized to prescribe oxygen cylinders:

- Board-certified pulmonologists
- Board-certified internists/ paediatricians/cardiologists
- Other qualified specialists as deemed appropriate by the Ministry of Health

Evaluation Requirements: The prescriber must:

- Review the patient's medical history and current health status.
- Conduct a comprehensive clinical evaluation of the patient, including the rationale for the oxygen therapy, the prescribed flow rate, and the duration of use.
- Perform necessary diagnostic tests (e.g., arterial blood gases, pulse oximetry) to confirm the need for oxygen therapy.

Duration of Prescription:

- The initial prescription for oxygen cylinders is typically valid for a period of 1 to 3 months, depending on the patient's condition and response to therapy.
- At the end of the prescribed period, a follow-up evaluation must be conducted to reassess the patient's oxygen needs. Based on this evaluation, the prescription can be renewed.

B. Continuous positive airway pressure (CPAP)

1. **Prescription criteria for** Standard **CPAP in adults: Must meet all of the following criteria:**
    1. The patient has moderate or severe obstructive sleep apnea (OSA) as determined by both clinical evaluation and sleep study.
    2. The sleep study must be performed at a facility-based sleep laboratory or through a home-based sleep test under the direction and control of a board-certified sleep specialist, and the sleep study results should show EITHER of the following parameters:
        a. Apnea-hypopnea index (AHI) > 15 events per hour or
        b. AHI is between 5-14 events per hour when accompanied by symptoms of OSA (e.g., excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia) or when

the individual has hypertension, ischemic heart disease, or a history of stroke.

3. The sleep study result or report must be verified and signed by a board-certified sleep specialist. The report must be no more than 30 days before the date of the prescription for the CPAP device.
4. A close follow-up date (no later than 60 days after dispensing the device) with the sleep specialist has been determined to assess the benefits of the device and the compliance of the patient.

2. **Prescription criteria for CPAP in pediatrics: Must meet all of the following criteria**

CPAP is an appropriate option for children with moderate or severe OSA and any of the following:

a. Minimal adenotonsillar tissue
b. Persistent OSA despite adenotonsillectomy
c. Craniofacial abnormalities.
d. Adenotonsillectomy is contraindicated (eg, too risky)
e. Strong preference for a nonsurgical approach

PLUS: All of the following:

a. The evaluation of sleep apnea and prescription of CPAP are both made by a board-certified pediatric sleep specialist.
b. The child weighs 30 kilograms or more.
c. Documentation of how sleep disturbance reduces the quality of life and affects the activities of daily living.
d. Sleep or respiratory study documenting two or more of the following:
    I. Oxygen saturation of less than 90 percent by pulse oximetry or partial pressure of transcutaneous or arterial oxygen of less than 60mm Hg.
    II. Carbon dioxide greater than 55 mmHg by end tidal, transcutaneous, arterial, or capillary blood measurement: and
    III. Apnea of 10 to 20 seconds duration on average of one per hour (AHI > 5).

C. Coverage criteria for Auto-titrating CPAP (APAP)

Treatment with APAP is appropriate when the patient meets all the following conditions:

1. The patient with confirmed severe OSA.

2. The patient has gone through an adequate CPAP trial, which has either failed or was not tolerated due to repeated inaccurate titration attempts.
3. Re-evaluation after the CPAP trial by the treating physician has concluded that APAP is preferable to in-lab titration or to switching to other devices like BiPAP.
4. In-lab CPAP titration cannot be done due to medical reasons.
5. The patient has NONE of the following contraindications to the use of APAP:
    a. Age 18 years or younger.
    b. Congestive heart failure.
    c. Chronic obstructive pulmonary disease.
    d. Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour)
    e. Neuromuscular disorders affecting respiration (e.g., muscular dystrophy, myasthenia gravis, etc.).
    f. Obesity hypoventilation syndrome (OHS): OHS is a diagnosis of exclusion that can be made when the following criteria are met:
        i. Awake alveolar hypoventilation as indicated by a partial arterial pressure of carbon dioxide >45 mmHg.
        ii. Alternative causes of hypercapnia and hypoventilation have been excluded

D. Follow up after dispensing Auto CPAP/(APAP/CPAP) (adult and pediatric patients)

I. Patients must be reassessed in the sleep clinic after a period of 6-8 weeks
II. Documentation of compliance through retrieval of the compliance report from APAP/CPAP machine.
III. Compliance is defined as follows:
    a. Use of the APAP/CPAP device for greater than or equal to 4 hours per night for at least 70% of the nights
    b. Any patient who is not compliant should receive education about compliance and be given another chance to check the compliance in 6-8 weeks
    c. If the patient proves not compliant or not willing to use the machine, the treatment physician or his designee should reclaim the machine and prepare it to be used by another patient.

E. Bilevel Positive Airway Pressure Device (BiPAP)

The criteria for prescribing must meet ALL the criteria below:

A. The prescribing physician must be pulmonary board-certified.
B. The prescription must include pressure setting, duration of use, and time of use.
C. A board-certified pulmonologist must have diagnosed the patient with one of the following chest conditions:

I. **Restrictive thoracic disorders causing respiratory failure** (i.e., severe neuromuscular diseases or severe thoracic cage abnormalities.:

a. The patient has symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), such as daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, and cognitive dysfunction.
b. Documentation of the patient has clinically significant blood gas abnormalities, as indicated by any of the following:
    a. An arterial blood gas PaCO2, done while awake and breathing the patient's usual FIO2 (fractional inspired oxygen concentration), is greater than or equal to 45 mm Hg; or
    b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88 % for at least 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the patient's usual FIO2; or
    c. For progressive neuromuscular disease only; maximal inspiratory pressures less than 60 cm H20 or forced vital capacity (FVC) less than 50 % predicted.

II. Severe chronic obstructive pulmonary disease (COPD): must have ALL of the following findings:
    a. The patient has symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), such as daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, cognitive dysfunction, etc., and
    b. The patient has an arterial blood gas PaCO2 greater than or equal to 52 mm Hg; and

c. Sleep oximetry demonstrates oxygen saturation less than or equal to 88 % for at least 5 cumulative minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at 2 liters/minute or the patient's prescribed FIO2, whichever is higher.

III. Obesity hypoventilation syndrome (OHS) when **all of the** following criteria are met:

a. BMI >30
b. Hypoxemia: PaO2 (arterial oxygen partial pressure) ≤ 60 mmHg or oxygen saturation (SpO2) ≤ 90% at rest.
c. Hypercapnia: PaCO2 (arterial carbon dioxide partial pressure) > 45 mmHg, especially during daytime or sleep.
d. Excluding other causes of respiratory failure, including documentation of FEV1/FVC greater than or equal to 70%.

F. BiPAP with Backup Rate

BiPAP with a backup rate provides an additional level of support for patients who may have periods of insufficient respiratory efforts. **Indications for Backup Rate in BiPAP:**

- **Chronic Respiratory Insufficiency:**
  - Patients may be at risk for periods of hypoventilation or apnea due to underlying respiratory conditions (e.g., severe neuromuscular disease or severe kyphoscoliosis, obesity hypoventilation syndrome, central hypoventilation syndrome (apnoea), and severe obstructive pulmonary disease).
  - Must be prescribed by Board board-certified pulmonologist
  - A pulmonologist must indicate the BiPAP pressure and backup respiratory rate.
  - Follow-up clinic visit must be arranged in 6-8 weeks to reassess the patient's condition and compliance with a machine similar to the above (CPAP/BIPAP) compliance

G. CPAP/BPAP interfaces replacement coverage

Replacement of any of the interfaces below for use with CPAP, APAP, or BiPAP is medically necessary at a frequency of no more often than every three months.
ANY ONE of the following interfaces for use with CPAP, APAP, or BiPAP as medically necessary:

A. Nasal mask.
B. Nasal pillows/prongs.
C. Full face mask.
D. Oral mask.

H. Other respiratory equipment

1.1.1. Nebulizer Machines:
The use of a nebulizer machine is medically **necessary for any of the** following indications:

I. To administer nebulized antibiotics (e.g., gentamicin, amikacin, or tobramycin, colistin, aztreonam) to patients with cystic fibrosis or bronchiectasis who need regular nebulized antibiotic treatments or for multi-drug-resistant P. aeruginosa pneumonia failing to improve on IV antibiotics therapy.
II. For patients with tracheobronchial stents.
III. For patients with tracheostomy or patients on chronic ventilation.
IV. To administer dornase alfa (Pulmozyme) or other mucolytics (e.g, acetylcysteine) for persistent thick or tenacious respiratory secretions in patients with cystic fibrosis or primary ciliary dyskinesia who need regular nebulized treatments.
V. To administer iloprost (Ventavis) to patients with pulmonary hypertension.
VI. To administer pentamidine to immunocompromised patients (e.g HIV, organ transplant recipients, etc.) as primary or prophylactic therapy for Pneumocystis jirovecii.
VII. To administer nebulized beta-agonists, anticholinergics, or corticosteroids, for the management of chronic airway diseases (e.g., COPD, asthma, bronchiectasis, etc.) if all the following conditions are met:
    i. An appropriate inhaler device (with/without a reservoir or spacer device) has been chosen by the treating physician. AND
    ii. The patient remains symptomatic despite adequate and proper use of inhaler medications using maximum tolerated doses of standard combination drugs (e.g. LABA/ICS, LABA/LAMA etc.). AND

iii. The patient must already be on add-on treatments (e.g., ICS/LABA combination, leukotriene modifiers in asthma etc.) or the treating physician must have considered that their use will not add any clinical benefits. AND
iv. The treating physician must document that the patient has been adherent to his/her regular treatments which include consistent, correct use of the inhaler device. AND
v. The treating physician must have considered and made an adequate effort to control comorbidities that are known to interfere with disease control (GERD, CRS, heart failure etc.).

1.1.2. Respiratory suction devices:

Must meet all the criteria below:

A. The patient has a chronic respiratory condition that result in copious respiratory secretions which require regular suctioning.
B. The patient has difficulty clearing secretions due to:
   I. Cancer or surgery of the throat or mouth.
   II. Dysfunction of the swallowing muscles.
   III. The patient is unconscious or has in a barely conscious state; or
   IV. The patient has a tracheostomy tube.

1.1.3. Pulse oximeter devices:

Pulse oximeter is a non-invasive and convenient method used to measure the real-time oxygen saturation level (SpO2) of a patient's blood.

The indications for prescribing a pulse oximeter must meet the following two criteria:

A. Prescription made by a board-certified pulmonologist.
B. The patient has one of the following conditions:
   I. Patient known to have respiratory failure
   II. Patient is on a ventilator
   III. Have a tracheostomy tube or
   IV. Use an oxygen therapy device at home or

1.1.4. Air Humidifiers:

Air Humidifier prescription must meet any of the following conditions:

A. The patient is on CPAP, BPAP, or oxygen therapy for medically necessary indications.
B. The patient is with tracheostomy.

1.1.5. High Frequency Chest Wall Oscillation Devices:

High frequency chest wall oscillation devices are prescribed provide the following criteria are met:

A. Evaluation and prescription of the High Frequency Chest Wall Oscillation Devices is made by a board-certified pulmonologist.
B. The patient has one of the following conditions:

I. Cystic fibrosis, which has been diagnosed through genetic testing or sweat chloride test plus radiological imaging.
II. Bronchiectasis, which has been confirmed by a high-resolution, spiral, or standard CT scan and which is characterized by:
    i. Daily productive cough for at least 6 continuous months; or
    ii. Frequent (i.e., more than 2/year) exacerbations requiring antibiotic therapy.
III. Advanced neuromuscular disease affecting the respiratory muscles.

C. There must be a well-documented failure of standard treatments to adequately mobilize retained secretions.

Appendixes

Appendix 1 ECG signs of pulmonary hypertension

1. **Right Ventricular Hypertrophy (RVH)**
   - **Criteria:** Signs of RVH can include:
     - **Tall R waves in V1:** An R wave greater than 7 mm.
     - **Deep S waves in V6:** An S wave deeper than 3 mm or more than half the height of the R wave.
     - **Right Axis Deviation:** A mean QRS axis greater than +90 degrees.
2. **Right Atrial Enlargement (RAE)**
   - **Criteria:** RAE is suggested by:
     - **Peaked P waves:** Specifically in lead II, with a height greater than 2.5 mm (known as P pulmonale).
     - **Duration:** P waves longer than 0.12 seconds.
     - **Biphasic P wave in V1:** A larger positive component compared to the negative component.
3. **Right Bundle Branch Block (RBBB)**
   - **Criteria:** RBBB may indicate significant right ventricular strain associated with chronic pulmonary hypertension. Look for:
     - **Wide QRS Complex:** Greater than 0.12 seconds.
     - **rSR' Pattern:** In leads V1 and V2, along with a wide S wave in leads I and V6.
4. **Signs of Right Ventricular Strain**
   - **Criteria:** Signs that indicate RV strain may include:
     - **Inverted T waves** in right precordial leads (V1 to V3).
     - **ST Segment Depression** in those same leads.
5. **Sinus Tachycardia**
   - **Criteria:** A heart rate exceeding 100 beats per minute can indicate a compensatory response to decreased cardiac output due to chronic pulmonary hypertension.