Learning Objectives:

1. Review the indications for chronic supplemental oxygen
2. Discuss the differences between standard continuous oxygen and oxygen conserving devices
3. Practice completing a certificate of medical necessity for supplemental oxygen
4. Review inhaler delivery devices and varied mechanisms of drug delivery

Scenario:
Mr. Shah is a 52-year-old male with severe COPD (FEV1 25% predicted). He notes a persistent decrement in his exercise tolerance over the last 6-8 months and chronic daily cough. He is currently on tiotropium and fluticasone/salmeterol. He has not had any recent exacerbations in the last year. His exam is remarkable for decreased breath sounds bilaterally. His vitals are normal and his oxygen saturation at rest is 94% on room air. You review his testing from today and note that he had a six-minute walk test today that showed a saturation of 85% on room air with exertion. He walked 824 feet.

Question 1: What is the approximate conversion from liters per minute to FiO2? If someone is on 40% FiO2 in the hospital, approximately what flow rate via nasal cannula should you expect they will need?

Each additional liter per min in oxygen flow increases the FiO2 by approximately 4%. A patient using 2LPM is inspiring approximately 28% FiO2 (room air is 21% FiO2). This estimate assumes a normal total minute ventilation and may be less accurate in acutely ill patients.
Question 2: What is the benefit of supplemental oxygen in chronic lung disease?

Approximately one million patients per year receive long term oxygen therapy through Medicare alone, costing over 2 billion dollars annually. The benefits of long term oxygen use are best described in patients with COPD. Patients with more severe chronic hypoxemia (PaO2<55 or SpO2< 88%) are most likely to attain mortality benefits as seen in the Nocturnal Oxygen Therapy Trial (NOTT) and the Medical Research Council (MRC) trial. In those with severe resting hypoxemia supplemental oxygen may also improve quality of life, cardiovascular morbidity, depression, cognitive function, exercise capacity and frequency of hospitalization. In contrast to this, the LOTT study noted that adding long term supplemental oxygen to those with stable COPD and with moderate resting desaturation or moderate exercise desaturation (SpO2 89-93% or SpO2<90% for ≥10s and ≥80% for ≥5 minutes while walking) did not result in improvement in mortality, all cause first hospitalization, quality of life, lung function or walk distance.

Figure 2. Overall mortality observed in the Nocturnal Oxygen Therapy Trial as a function of time from randomization. The top line (open circles) represents those in the continuous O2 therapy group. The bottom line (open squares) represents nocturnal O2 therapy group. From the NOTT trial, Annals of Internal Medicine 1980.

Question 3: What are the different ways in which home oxygen therapy is delivered? What is the difference between continuous and pulse dose oxygen therapy?

Continuous flow oxygen is oxygen delivered at a constant rate, regardless of respiratory rate. Pulse dose oxygen is delivered during inspiration only. The quantity of oxygen delivered in this method is influenced by the respiratory rate. There is no oxygen flow while the patient exhales.

Question 4: Would Mr. Shah qualify for long term oxygen therapy? What are the indications for chronic supplemental oxygen therapy? What testing do you need to qualify for oxygen?

The patient should have a chronic lung disease (ex: COPD, ILD, CF, bronchiectasis, malignancy, etc) and/or hypoxia-related symptoms or findings (ex: pulmonary hypertension, congestive heart failure due to cor pulmonale, erythrocytosis, morning headaches, etc). It is important to note that measurement of cutaneous oxygen saturation by pulse oximetry is not as reliable as measurement of PaO2 in establishing the presence of hypoxemia. However, to qualify for home oxygen therapy, most insurance providers follow the criteria as outlined by the Centers for Medicare and Medicaid Services which requires either:
- \( \text{PaO}_2 \leq 55 \text{ mmHg or SpO}_2 \leq 88\% \) on room air at rest or with exertion
- \( \text{PaO}_2 \leq 59 \text{ mmHg or SpO}_2 \leq 89\% \) if there is evidence of cor pulmonale, right heart failure or erythrocytosis (Hct>55%)

Oxygen flow is typically titrated to achieve a target SpO2>90% or PaO2> 60-80 mmHg. From long term oxygen therapy initiation, median survival in patients with COPD is typically around 24-36 months.

For safety reasons, patients who smoke cigarettes and e-cigarettes should not be prescribed long term oxygen therapy.6

Nocturnal Oxygen Supplementation requires:

- \( \text{SpO}_2 < 88\% \) during sleep for \( \geq 5 \) cumulative minutes OR, decrease in \( \text{SpO}_2 > 5\% \) during sleep for \( \geq 5 \) cumulative minutes, minimum 2-hour test time

Of note, a complete “face to face” encounter is required by CMS within 30 days of signing the CMN form. During the COVID-19 pandemic health emergency, a telemedicine visit was allowed to fulfill this requirement.

Qualifying testing should include:

- room air resting saturations<88%
- room air exertion (hallway or stair walking) saturations
- if exertional saturations < 88%, repeat testing on 2L/min oxygen
- continue to titrate 3, 4, 6, 8, 10 L/min as needed to attain sat >89%
- If the patient needs 6L/min or higher, CMS requires testing results on 4L/min plus at higher levels

You must document that the addition of supplemental oxygen treats the hypoxemia (i.e. that on 2LPM of supplemental oxygen saturations remain above 89%).

**Scenario Continued:**
Mr. Shah does additional testing and it’s determined that he requires 2LPM to maintain a saturation of 93% with exertion.

**Question 5:** You are preparing to write a prescription for Mr. Shah’s home oxygen. What elements must be included?

The prescription must include the following:

- Length of need, date of order, signature, NPI, L/min
- Specific equipment requested
  - Stationary equipment-liquid or concentrator (normal is up to 5L/min, specific high flow if pt needs >5 L/min)
  - Portable equipment
    - specify if pulse or intermittent flow
    - specify if conserving device
    - accessories backpack, cart humidifier
- If he has Medicare insurance, you will also need to complete a certificate of medical necessity (CMS form 484). An example form for Mr. Shah is included as an appendix.
**Question 6:** As you begin writing his oxygen prescription you debate what types of portable equipment to offer Mr. Shah. What types of oxygen delivery devices are available?

Standard supplementation is typically provided with continuous flow nasal canula. Stationary oxygen delivery systems typically limit patients to the confines of 50 feet of tubing from the concentrator. However, there are alternative modes of oxygen delivery, particularly for those patients who are more severely hypoxemic and or want to be more active outside of the confines of their own home. Portable oxygen delivery devices are compact enough to be carried or wheeled outside the home. Oxygen conserving devices attempt to deliver oxygen more efficiently and can be added to most delivery systems. Examples of portable oxygen delivery devices and oxygen conserving systems are outlined in the following tables.

<table>
<thead>
<tr>
<th>Max pulse dose</th>
<th>Max continuous flow</th>
<th>Hours system lasts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>E tank</strong> (standard tank on cart)</td>
<td>5</td>
<td>10-15</td>
</tr>
<tr>
<td><strong>M6 tank</strong> (smaller tank with carrier bag)</td>
<td>5</td>
<td>5-normal regulator 10-High flow regulator</td>
</tr>
<tr>
<td><strong>Portable oxygen concentrator</strong></td>
<td>1-4 PD most commonly 5-6 PD less common 7-9 PD rare</td>
<td>3</td>
</tr>
<tr>
<td><strong>Liquid oxygen (Helios Marathon)</strong></td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td><strong>Liquid oxygen (Companion 1000T)</strong></td>
<td>6</td>
<td>15</td>
</tr>
</tbody>
</table>


When prescribing portable oxygen systems, the tanks should ideally weigh less than 10 lbs, be able to provide at least a 4 hr supply and be easily carried by the patient.
<table>
<thead>
<tr>
<th>Type of System</th>
<th>Ambulatory Component</th>
<th>Stationary Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lightweight compressed gas system</td>
<td>Small, pre-filled tanks delivered to you on a weekly basis, depending on how much oxygen you are using, or tanks that fill overnight at home (aka a <em>homefill system</em>) from your concentrator. Carried in a bag rather than a cart. Good for patients who are highly mobile and active.</td>
<td>Stationary concentrator: Homefill compressed gas system: concentrator on the bottom, filling station on the top:</td>
</tr>
<tr>
<td>Liquid oxygen system</td>
<td>Small, refillable thermos-like tank which you fill from the reservoir as needed. Smallest and most portable. (~3.5 lbs). Often combined with pulse device or reservoir canula to maximize efficiency. Some oxygen may bleed off into the atmosphere, decreasing how long it lasts; may freeze in cold weather</td>
<td>Oxygen reservoir used with 50 ft tubing</td>
</tr>
<tr>
<td>Portable oxygen concentrator (POC)</td>
<td>A small electrical device that runs on regular electricity or on a battery, is easily recharged even in a car, and requires no tanks or filling. The maximum tubing length for proper delivery of oxygen is 7 feet. <em>These units can be taken onto airplanes.</em></td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Summary of varied oxygen delivery systems.
Ultimately you decide to prescribe Mr. Shah 2L PM using a lightweight compressed gas system. You review his home inhalers and ask him to demonstrate his inhaler technique. He is on fluticasone/salmeterol HFA, tiotropium respimat and albuterol MDI PRN. He is confused by all the different devices and isn’t sure of the best way to use each of them.

**Question 7:** How do you instruct Mr. Shah on the use of his inhalers. What is the difference between each of the delivery devices?

<table>
<thead>
<tr>
<th>Class</th>
<th>Examples</th>
<th>Mechanism</th>
<th>Comments/Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDI (metered dose inhaler)</td>
<td></td>
<td>Pressurized canister contains the drug suspended in a mixture of propellants, surfactants,</td>
<td>Most popular, oldest Convenience, good lung-to-oropharynx distribution with spacer</td>
</tr>
<tr>
<td>with CFC or HFA</td>
<td></td>
<td>propellant in most inhalers.</td>
<td>Requires coordination, spacer is cumbersome and still some environmental impact</td>
</tr>
<tr>
<td>DPI (dry powder inhaler)</td>
<td></td>
<td>Breath actuated device; drug is delivered to the airways by the inhalation of air over a</td>
<td>Easier to use than HFA, less coordination needed, drug stable for longer and no environmental</td>
</tr>
<tr>
<td></td>
<td></td>
<td>punctured capsule, blister, or reservoir; need sufficient inspiratory flow rates to deliver</td>
<td>impact; less dose uniformity and dependent on patient inspiratory force</td>
</tr>
<tr>
<td>Soft mist inhaler (SMI)</td>
<td></td>
<td>Drug in solution in cartridge, patient twists device storing energy in spring, when patient</td>
<td>Combines advantages of MDI and nebulizers; Propellant free, portable and better lung-to-oropharynx</td>
</tr>
<tr>
<td></td>
<td></td>
<td>presses button spring release and pushes liquid into uniblock with 2 channels that produce</td>
<td>delivery than MDI but not as good as MDI+valved holding chamber</td>
</tr>
</tbody>
</table>

Table 3. Summary of varied inhaler types, mechanisms of delivery and instructions for use.
All delivery devices are equivalent in terms of patient outcomes based on multiple meta-analyses and systematic reviews. Selection of inhaler should be based upon convenience, patient preference and insurance coverage. Common problems with inhaler use include improper technique/difficulty with coordination of actuation and inhalation, deposition of drug in the oropharynx, and insufficient breath hold. Use of a spacer or valved holding chamber with an MDI can improve delivery of drug to the airways and minimize deposition in the oropharynx. Spacers are not used with DPI or SMI devices.

When prescribing inhaled therapies, education and training on the use of these devices is paramount. Studies indicate that errors of inhaler use are common and that higher inhaler error is significantly associated with poor disease outcomes. Having a patient talk you through the steps of their technique is better than simply asking them if they are using their inhalers, but having them show you in real-time is best.

There are also multiple resources available online to help with inhaler education including videos available in multiple languages. A few examples include:

- [https://www.cdc.gov/asthma/inhaler_video/default.htm](https://www.cdc.gov/asthma/inhaler_video/default.htm)
- [http://use-inhalers.com](http://use-inhalers.com)

**References:**

**CERTIFICATE OF MEDICAL NECESSITY**

**CMS-484—OXYGEN**

**SECTION A: Certification Type/Date:** INITIAL 06/26/20, REVISED 05/26/21, RECERTIFICATION 06/26/21

<table>
<thead>
<tr>
<th>PATIENT NAME, ADDRESS, TELEPHONE and MEDICARE ID</th>
<th>SUPPLIER NAME, ADDRESS, TELEPHONE and NSC or NPI #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wessie Shah, 632 kicland Avenue, Winston Salem NC</td>
<td>Aerocare Greensboro: West Friendly Avenue Limits B &amp; F, Greensboro, NC 2741</td>
</tr>
<tr>
<td>(8.6.5). 2 3 0 - 6 3 3 1 Medicare ID 1EG4-TE5-MK72</td>
<td>(3.3.6). 6 8 7 8 4 NSC or NPI #</td>
</tr>
</tbody>
</table>

**PLACE OF SERVICE:** Supply Item/Service Procedure Code(s)

<table>
<thead>
<tr>
<th>NAME and ADDRESS of FACILITY if applicable (see reverse)</th>
<th>PHYSICIAN NAME, ADDRESS, TELEPHONE and UPIN or NPI #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Physician Izquierdo Medical Center Boulevard Winston Salem, NC</td>
</tr>
</tbody>
</table>

**SECTION B: Information in this Section May not Be Completed by the Supplier of the Item Supplies.**

**EST. LENGTH OF NEED (# OF MONTHS): 99 1-99 (99=LIFETIME)**

**DIAGNOSIS CODES:** 86.11

**ANSWERS**

**ANSWER QUESTIONS 1-9. (Check Y for Yes, N for No, or D for Does Not Apply, unless otherwise noted.)**

<table>
<thead>
<tr>
<th>Qn</th>
<th>a) mm Hg</th>
<th>b) %</th>
<th>c) / /</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Qn 1 2 3**

1. Enter the result of recent test taken on or before the certification date listed in Section A. Enter (a) arterial blood gas PO2 and/or (b) oxygen saturation test; (c) date of test.

2. Was the test in Question 1 performed (1) with the patient in a chronic stable state as an outpatient, (2) within two days prior to discharge from an inpatient facility to home, or (3) under other circumstances?

3. Check the one number for the condition of the test in Question 1: (1) At Rest; (2) During Exercise; (3) During Sleep

4. If you are ordering portable oxygen, is the patient mobile within the home? If you are not ordering portable oxygen, check D.

5. Enter the highest oxygen flow rate ordered for this patient in liters per minute. If less than 1 LPM, enter an "X."

6. If greater than 4 LPM is prescribed, enter results of recent test taken on 4 LPM. This may be an (1) arterial blood gas PO2 and/or (b) oxygen saturation test with patient in a chronic stable state. Enter date of test (c).

**ANSWER QUESTIONS 7-9 ONLY IF PO2 = 56-59 OR OXYGEN SATURATION = 89 IN QUESTION 1**

<table>
<thead>
<tr>
<th>Qn</th>
<th>a) mm Hg</th>
<th>b) %</th>
<th>c) / /</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Qn Y N**

7. Does the patient have dependent edema due to congestive heart failure?

8. Does the patient have cor pulmonale or pulmonary hypertension documented by P pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement?

9. Does the patient have a hematocrit greater than 56%?

**NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):**

**NAME**

**TITLE**

**EMPLOYER**

**SECTION C: Narrative Description of Equipment and Cost**

(1) Narrative description of all items, accessories and options ordered; (2) Suppliers charge; and (3) Medicare Fee Schedule Allowance for each item, accessory, and option (see instructions on back)

Patient will need portable oxygen concentrator, oxygen tanks, and stationary concentrator. Will also need nasal canulas and extension tubing. Allow for 6 tanks per week, 3 nasal canulas per month and accessory tubing.

**SECTION D: PHYSICIAN Attestation and Signature/Date**

I certify that I am the treating physician identified in Section A of this form. I have reviewed Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached herein, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and understand that any falsification, omission, or concealment of material fact in this section may subject me to civil or criminal liability.

**PHYSICIAN’S SIGNATURE**

**DATE 5.00 / 26.06 / 21.03**

| Form: CMS-484 (11/16) |

© 2022 Association of Pulmonary and Critical Care Medicine Program Directors