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Oxygen Delivery Devices and Inhaler Technique

An APCCMPD Ambulatory Care Curriculum Teaching Script

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Oxygen Delivery Devices and Inhaler Technique

Scenario 1:

Mr. Shah is a 58-year-old man with advanced COPD (FEV1 25% predicted). He notes a progressive 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 exacerbations in the last year. His exam is remarkable for decreased breath sounds bilaterally. His vitals are normal except for his oxygen saturation which is 94% at rest on room air. You review his testing 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?

Question 2:
What is the benefit of supplemental oxygen in chronic lung disease?

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?

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?

Scenario 1 (Continued):

On room air, Mr. Shah desaturates to SpO2 86% during exertion. He requires 2 liters/min (LPM) to maintain SpO2 90% while walking.

Question 5:
Mr. Shah mentioned that he had a difficult time handling the oxygen tank used during his titration due to its weight. What types of oxygen delivery devices are available for use at home?

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Scenario 1 (Continued):

Ultimately you decide to prescribe Mr. Shah 2 LPM oxygen using a lightweight compressed gas system.

Question 6:
You are preparing to write a prescription for Mr. Shah's home oxygen. What elements must be included?

Scenario 1 (Continued):

You review Mr. Shah's 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?

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Oxygen Delivery Devices and Inhaler Technique

Educational Objectives:

1. Review indications for chronic supplemental oxygen
2. Discuss 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

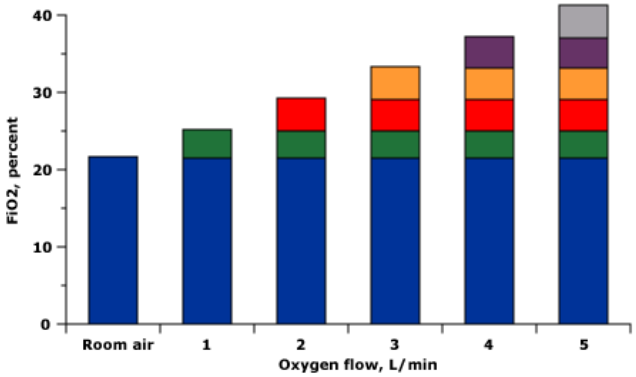
Scenario 1:

Mr. Shah is a 58-year-old man with advanced COPD (FEV1 25% predicted). He notes a progressive 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 exacerbations in the last year. His exam is remarkable for decreased breath sounds bilaterally. His vitals are normal except for his oxygen saturation which is 94% at rest on room air. You review his testing 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 FiO_2? If someone is on 40% FiO_2 in the hospital, approximately what flow rate via nasal cannula should you expect they will need?

Each additional liter per minute (LPM) in oxygen flow increases the FiO_2 by approximately 4%. Room air is 21% FiO2, so a patient using 2 LPM is inspiring approximately 28% FiO_2. This estimate assumes a normal total minute ventilation and may be less accurate in acutely ill patients.[1] Figure 1 shows the estimated inspiratory oxygen concentration by nasal cannula flow rate.

Figure 1. Oxygen Delivery via Nasal Cannula and Estimated FiO_2



**Each additional stacked colored block represents approximately 4% increase in FiO2.*
Reproduced from "Portable oxygen delivery and oxygen conserving devices." UpToDate 2024.[2]

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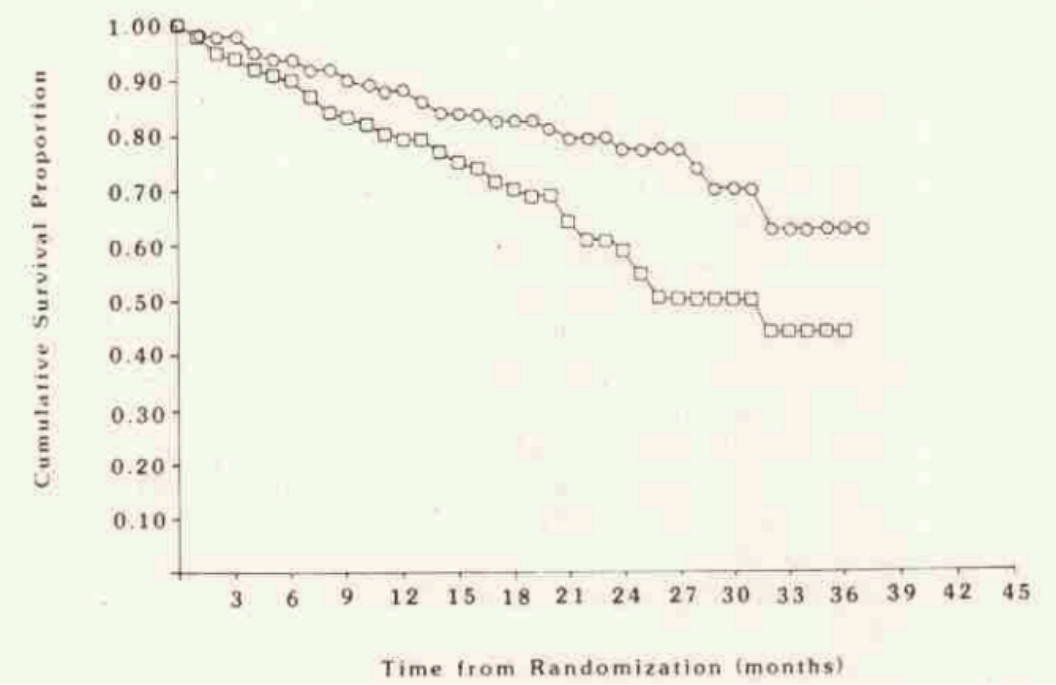
Question 2: What is the benefit of supplemental oxygen in chronic lung disease?

Approximately one million patients per year receive long term oxygen therapy (LTOT) through Medicare alone, costing over $2 billion annually.[3] LTOT has been most well studied in patients with COPD. Patients with severe chronic resting hypoxemia ($PaO_2 \leq 55$ mm Hg or $SpO_2 \leq 88\%$) treated with continuous oxygen supplementation experience a mortality reduction, as seen in the Nocturnal Oxygen Therapy Trial (NOTT) and the Medical Research Council (MRC) trial.[4,5] 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. Figure 2 from this study illustrates a statically significant reduction in overall mortality at 12 and 18 months in patients with severe hypoxemia on continuous O_2 therapy compared to nocturnal O_2 therapy (<15 hours per day).

Figure 2. Overall Mortality Reduction with Continuous vs Nocturnal Oxygen Therapy



**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 O_2 therapy group. The bottom line (open squares) represents nocturnal O_2 therapy group.*
From the NOTT trial, Annals of Internal Medicine 1980.[4]

Conversely, the Long-Term Oxygen Treatment Trial (LOTT) found that adding LTOT to those with stable COPD and either moderate resting hypoxemia (SpO_2 89-93%) or moderate exercise desaturation ($SpO2 \geq 80\%$ for ≥ 5 minutes and $SpO_2 < 90\%$ for ≥ 10 seconds during a six minute walk test) did **not** result in improvement in mortality, all cause first hospitalization, quality of life, lung function, or walk distance.[6] The 2020 ATS clinical practice guidelines concur with the findings of the LOTT and do not recommend LTOT for moderate hypoxemia.[7] Currently, there is no strong evidence for the use of nocturnal oxygen supplementation in patients with COPD with nocturnal desaturations but do not qualify for LTOT.[8]

Note that these results should not be generalized to other chronic lung disease populations with hypoxemia, such as interstitial lung disease and pulmonary hypertension.

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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, ensuring uninterrupted delivery.

Pulse dose (PD) oxygen is delivered during inspiration only, thus the quantity of oxygen delivered will be influenced by the respiratory rate. With PD oxygen, there is no oxygen flow while the patient exhales, thus conserving oxygen supply and improving efficiency. These are generally reserved for patients with lower oxygen requirements (<4 LPM).

It is important to keep in mind that PD setting numbers are not equivalent to liters per minute of oxygen delivery.[9] With PD oxygen, each device delivers a different amount of oxygen per setting—for example, a setting of "2" on one machine is not equivalent to a setting of "2" on a different machine.

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?

To qualify for LTOT, most insurance providers follow the criteria outlined by the Centers for Medicare and Medicaid Services (CMS) which require either:

- $PaO_2 \leq 55$ mmHg or $SpO_2 \leq 88\%$ on room air at rest or with exertion, or
- PaO_2 56-59 mmHg or $SpO_2 \leq 89\%$ if there is evidence of *cor pulmonale*, heart failure, or erythrocytosis with a hematocrit >56%

The measurement of cutaneous oxygen saturation by pulse oximetry is commonly used but is less accurate than measurement of PaO_2 via blood gas, particularly in individuals with darker skin complexion.[10,11] The patient should have a chronic lung disease (e.g., COPD, ILD, CF, etc.) and/or hypoxia-related symptoms or findings (as above). For safety reasons, many guidelines have recommended that smoking (cigarettes or e-cigarettes) is a contraindication to home oxygen therapy, though recent guidelines have been less stringent and emphasize the need for education on oxygen safety, including smoking cessation and fire prevention.[12]

Oxygen can be prescribed for continuous use, with exertion, or with sleep (though mortality benefit has been only shown with continuous use, as noted in Question 2). Oxygen flow is typically titrated to achieve a target SpO_2 >90% or PaO_2 > 60-80 mmHg. From initiation of long-term oxygen therapy, median survival in patients with COPD is typically around 24-36 months.

Nocturnal Oxygen Supplementation qualification requires either:

- An SpO2 ≤ 88% during sleep for > 5 cumulative minutes, or
- A decrease in arterial PaO_2 >10 mmHg or a decrease in SpO_2 >5% from baseline saturation and associated symptoms of hypoxemia (impairment of cognitive processes, nocturnal restlessness, or insomnia); minimum 2-hour test time required

Of note, a complete "face to face" encounter is required by CMS within 30 days of signing the certificate of medical necessity (CMN) form and recertification is required annually. Documentation must include a statement that the addition of supplemental oxygen effectively treats the hypoxemia (i.e., use of 2 LPM of supplemental oxygen maintains saturations above 89%).

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Qualifying testing should include:

- Resting saturations and exertional saturations on room air
- If saturations $\leq$ 88%, repeat testing on 2 LPM oxygen with titration as needed at rest or with exertion
- If the patient needs $\geq$ 4 LPM, CMS requires testing results on 4 LPM plus at the higher final flow rate

Scenario 1 (continued):

On room air, Mr. Shah desaturates to SpO_2 86% during exertion. He requires 2 LPM to maintain SpO_2 90% while walking.

Question 5: Mr. Shah mentioned that he had a difficult time handling the oxygen tank used during his titration due to its weight. What types of oxygen delivery devices are available for use at home?

Standard oxygen supplementation is typically provided with continuous flow nasal canula. Stationary oxygen delivery systems limit patients within 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 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 1-5.

Note that pulse dose settings do not automatically equate to continuous flows (i.e., PD setting 4 may not equal 4 LPM via continuous oxygen). These should be titrated in the appropriate setting to achieve target saturations. Tables 1 and 2 below detail portable oxygen devices and compare their capabilities and oxygen concentrator classifications, respectively.

Table 1. Summary of Portable Oxygen Devices

	Max pulse dose (PD)	Max continuous flow	Hours of usage
E tank (standard tank on cart)	5	10-15	-2-3 hours on 5 LPM -6-7 hours on 5 PD
M6 tank (smaller tank with carrier bag)	5	5-normal regulator 10-High flow regulator	-0.5-1 hour on 5 LPM -1-2 hours on 5 PD
Portable oxygen concentrator	1-4 PD most commonly 5-6 PD less common 7-9 PD rare	3	Single battery: -1-2 hours on 3 LPM -2-6 hours on 3 PD (patients can swap out batteries)
Liquid oxygen (Helios Marathon)	4	6	-2-3 hours on 5 LPM
Liquid oxygen (Companion 1000T)	6	15	-3-4 hours on 5 LPM

**Summary of portable oxygen devices.*

Adapted from Jacobs SS. Clinician Strategies to Improve the Care of Patients Using Supplemental Oxygen.[13]

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Table 2. Classification of Oxygen Concentrators

Classification of Oxygen Concentrators	
	Production Technique
Pressure Swing Absorption (PSA) Concentrators	- Prevalent in both home and hospital settings - Utilizes a molecular sieve to adsorb nitrogen from compressed air, leaving oxygen with a purity of 90–95% - Suitable for both stationary and portable - Flows adjustable from 0.5 to 15L/min
Membrane-Based Concentrators	- More prevalent in industrial applications; however, some research indicates potential for medical use - Uses a semi-permeable membrane to separate oxygen from other gases, based on differences in diffusivity and solubility - Can reach oxygen purity of 90% - Compact size/portable
Electrolytic Oxygen Generators	- Produce oxygen through the electrolysis of water, splitting it into hydrogen and oxygen using an electric current - Production flow of 1 L/min and stability exceeding 600hr - High purity oxygen up to 99% - Portable - Suitable for home use, particularly in areas with limited access to traditional oxygen supplies - Challenges include water supply requirement and higher initial costs
Chemical Oxygen Generators	- Generate oxygen using chemical reactions - Primarily used in emergency situations, such as oxygen in aircraft to passengers during cabin pressure loss - Limited duration - Challenges include that it is a fire hazard and requires replacement after use making it not suitable for medical use

**Summary of different classifications of oxygen concentrators.*
Adapted from Erdemir D et al. *A Review of Medical Oxygen Concentrators for Respiratory Applications.*[14]

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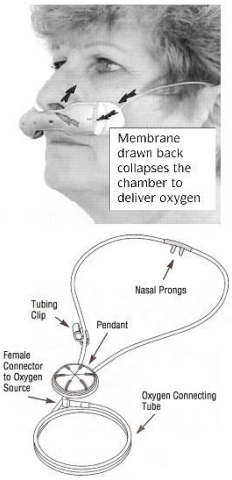
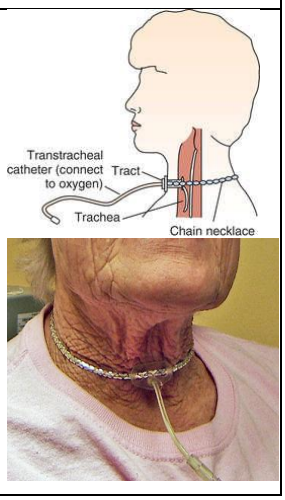
Table 3. Commercial Oxygen Concentrators

Commercial Oxygen Concentrators							
	Inogen at Home 5L	**Philips Respironics EverFlo**	**Drive Devilbiss 525 DS Quiet**	**Caire Companion**	**Inogen One G4**	**Respironics SimplyGlo Mini**	**iGlo2**
Type	Stationary	Stationary	Stationary	Stationary	Portable	Portable	Portable
O_2 Production Method	PSA	PSA	PSA	PSA	PSA	PSA	PSA
O_2 Delivery Method	Continuous	Continuous	Continuous	Continuous	Pulse	Pulse	Pulse
Flow (L/min)	Max 5L/min	Max 5L/min	Max 5L/min	Max 5L/min	Not specified	2 at flow settings 5	1 at flow settings 5
Oxygen purity (%)	87-95	90-96	87-96	90-96	Up to 90	87-96	Not specified
Weight (Kg)	8.2	31	16.3	16.3	1.31 without battery	2.7 with extended battery	2.25
Battery Life	N/A	N/A	N/A	N/A	Up to 5hr, 45 minutes at flow setting 1	Up to 9hr with extended battery	3.5hr at flow setting 2

*Comparison of Commercial Oxygen Concentrators. Adapted from Erdemir D, Dincer I. *A Review of Medical Oxygen Concentrators for Respiratory Applications*[14]

Table 4. Summary of Oxygen Conserving Devices

	Reservoir or Oxymizer (mustache, fluidic mustache or pendant)	**Demand pulse (Chad-oxymatic, Helios, EasyPulse, Impulse, etc.)**	**Demand pulse; Noninvasive open ventilator with oxygen (NIOV)**	**Transtracheal catheter (placed surgically)**
Photos				

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How it works	Stores O_2during exhalation; during inhalation patient receives stored O_2plus the supply O_2	Delivery of brief pulse of nearly 100% FiO_2 during early inspiration; can be stand alone, portable O_2concentrator, compressed gas	Wearable augmentation ventilator attached to portable O_2cylinder, delivers 50-250 mL boluses of pressurized O_2	Deliver O_2directly through opening in neck; bypass dead space; increase CO_2 elimination efficiency
Highest flow	16 LPM	n/a	Larger pulses	16 LPM
Efficiency	2:1 to 4:1	3:1 to 7:1	Not available	2:1 to 3:1
Pros	Inexpensive, simplest to use	Maximal O2 delivery; studies show good performance compared to NC	Studies show reduced dyspnea, higher exercise work rate, increased oxygenation	Reduced work of breathing, no tubing
Cons	Can be physically obtrusive	Audible pulses, mechanical failure (may require battery), variability in oxygenation	Cost	Requires surgical procedure; Can lead to tracheal desiccation and trouble with secretions

**When prescribing portable oxygen systems, the tanks should ideally weigh less than 10 lbs, be able to provide at least a 4-hour supply and be easily carried by the patient.*

Adapted from Porszasz J et al. *Physiologic effects of an ambulatory ventilatory system in chronic obstructive pulmonary disease.*[15]

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Table 5. Oxygen Delivery Systems

Type of System	Ambulatory Component	Stationary Component
Lightweight compressed gas system	Small, pre-filled tanks delivered on a weekly basis, depending on how much oxygen is required, or tanks that fill overnight at home (aka a *home-fill system*) from a concentrator. Carried in a bag rather than a cart. Good for patients who are highly mobile and active.  16	Stationary concentrator:  17 Home-fill compressed gas system: concentrator on the bottom, filling station on the top:  18
Liquid oxygen system	Small, refillable thermos-like tank filled 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  19	Oxygen reservoir, typically used with 50 feet of tubing
Portable oxygen concentrator (POC)	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. These units can be taken onto airplanes.	 17

**Summary of varied oxygen delivery systems.*
Adapted from Hardavellaet al. *Oxygen devices and delivery systems.*[2]

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Scenario 1 (continued):

Ultimately you decide to prescribe Mr. Shah 2 LPM oxygen using a lightweight compressed gas system.

Question 6: 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, LPM
- Specific equipment requested
    - Stationary equipment - liquid or concentrator (normal is up to 5 LPM, specific high flow if patient needs >5 LPM)
    - Portable equipment
        - specify if pulse or intermittent flow
        - specify if conserving device
        - accessories backpack, cart humidifier
- If a patient has Medicare, a certificate of medical necessity (CMS form 484) is also needed. An example form is included as an appendix.

Scenario 1 (continued):

You review Mr. Shah's 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?

All inhaler delivery devices are equivalent in terms of overall 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 devices, and only some SMIs (Spiriva Respimat). Table 6 describes the different types of available inhaler devices.

Table 6. Types of Inhaler Devices

Inhaler	Formulation	Metering System	Currently Available	Pros	Cons
Metered Dose Inhaler (MDI)	Drug suspended or dissolved in propellant (with surfactant and cosolvent)	Metering valve and reservoir	Several similar MDI actuators depending by manufacturers	-Compact and portable -consistent dosing and rapid delivery	-not breath-actuated -difficult to use if poor dexterity or weak grip strength
MDI with spacer	Same as above	Same as above	AeroChamber®, AeroChamber Plus®, OptiChamber®	-easy to coordinate -help decrease orophargnyeal deposition of the medication -higher lung deposition than MDI alone	-less portable -additional cost

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Dry Powder Inhaler (DPI)	Drug blend in lactose, drug alone, drug/excipient particles	Capsules, blisters, multidose blister packs reservoirs	Diskus®, Ellipta®, HandiHaler®	-compact and portable -breath actuated—do not require coordination of inhalation with activation -does not require hand strength -does not contain propellants	-requires a minimum inspiratory flow -not appropriate for emergency situations -many cannot use it correctly
Soft Mist Inhaler (SFI)	Aqueous Solution or suspension	Unit dose blisters or reservoirs Spring is released during inhaler use to force solution through a fine nozzle (uniblock)→two fine jets of liquid that converge and generate a soft mist	Respimat®	-compact and portable -relative long generation time of aerosol cloud facilitates coordination of inhalation and actuation -same level of efficacy and safety as MDI -does not contain propellants	-metered volume of 15µL limits the dose-delivery capacity of the marketed design to drugs with adequate solubility with respect to the required dose
Nebulizers	Aqueous solution or suspension	Nebule dispensed into reservoir chamber of nebulizer	Jet nebulizers, breath-actuated and breath-enhanced nebulizers, mesh nebulizers	-no inhalation technique required -able to aerosolize high doses of drugs that are not available with DPI or MDIs	-long treatment times -risk of bacterial contamination -need daily cleaning

**Different types of inhaler devices.*
Adapted from Rogliani et al.[20]

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 increased inhaler error is significantly associated with poor disease outcomes.[21] Having a patient teach back to you the steps of their technique is superior to simply asking them if they are using their inhalers. Having them demonstrate their technique for you in real-time is preferred.

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

- https://www.cdc.gov/asthma/caring/index.html
- https://www.lung.org/lung-health-diseases/lung-disease-lookup/asthma/treatment/deviceshttp://use-inhalers.com

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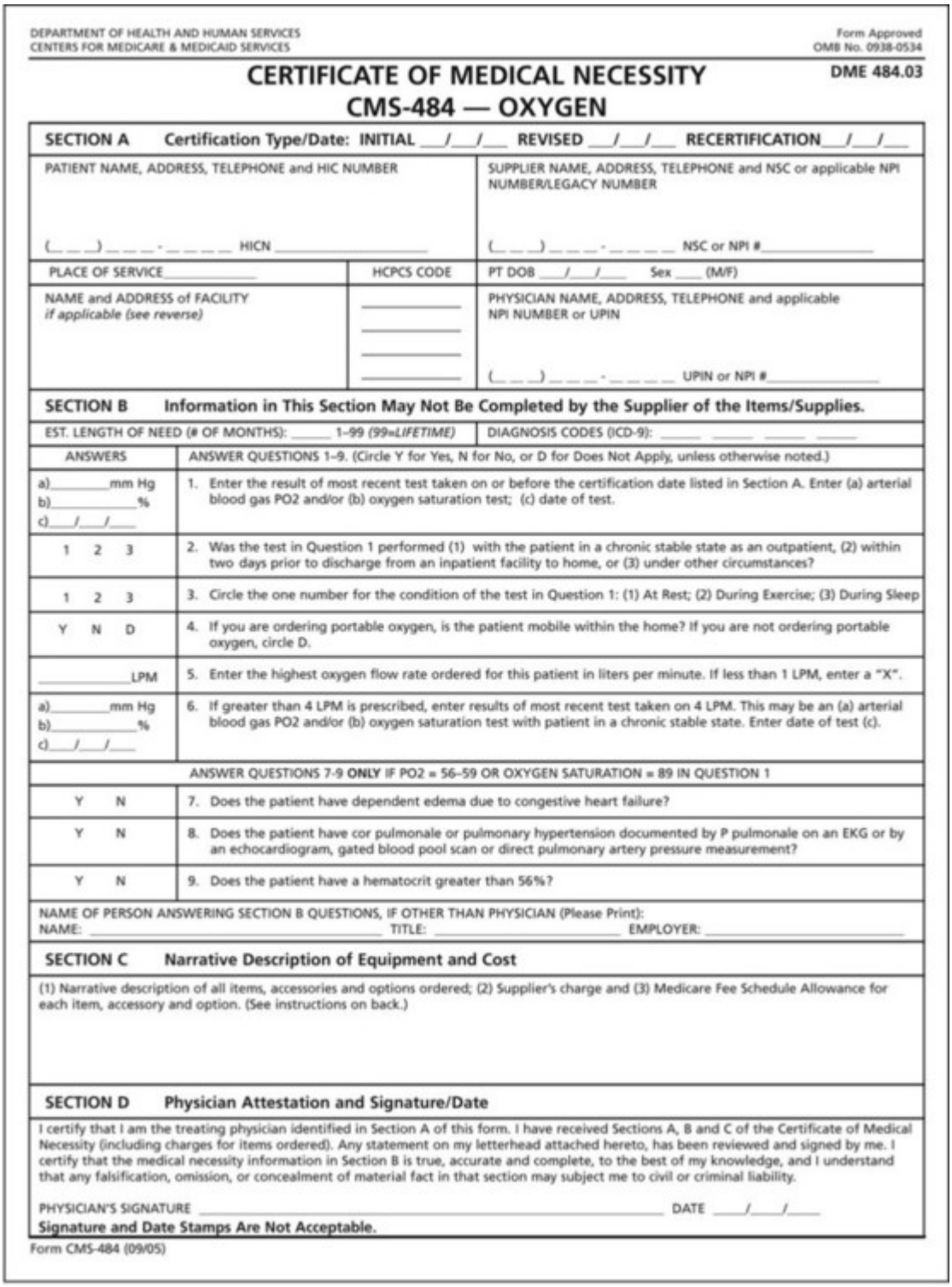
Appendix



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CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0534

CERTIFICATE OF MEDICAL NECESSITY
CMS-484 — OXYGEN

DME 484.03

SECTION A Certification Type/Date: INITIAL ___/___/___ REVISED ___/___/___ RECERTIFICATION___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER		SUPPLIER NAME, ADDRESS, TELEPHONE and NSC or applicable NPI NUMBER/LEGACY NUMBER
(__ __ __) __ __ __ - __ __ __ __ HICN _____		(__ __ __) __ __ __ - __ __ __ __ NSC or NPI #_____
PLACE OF SERVICE_____	HCPCS CODE	PT DOB ___/___/___ Sex ___ (M/F)
NAME and ADDRESS of FACILITY *if applicable (see reverse)*	_____ _____ _____ _____	PHYSICIAN NAME, ADDRESS, TELEPHONE and applicable NPI NUMBER or UPIN (__ __ __) __ __ __ - __ __ __ __ UPIN or NPI #_____

SECTION B Information in This Section May Not Be Completed by the Supplier of the Items/Supplies.

EST. LENGTH OF NEED (# OF MONTHS): _____ 1–99 *(99=LIFETIME)* | DIAGNOSIS CODES (ICD-9): _____ _____ _____ _____

ANSWERS	ANSWER QUESTIONS 1–9. (Circle Y for Yes, N for No, or D for Does Not Apply, unless otherwise noted.)
a)_____mm Hg b)_____% c)___/___/___	1. Enter the result of most 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.
1 2 3	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?
1 2 3	3. Circle the one number for the condition of the test in Question 1: (1) At Rest; (2) During Exercise; (3) During Sleep
Y N D	4. If you are ordering portable oxygen, is the patient mobile within the home? If you are not ordering portable oxygen, circle D.
_____LPM	5. Enter the highest oxygen flow rate ordered for this patient in liters per minute. If less than 1 LPM, enter a "X".
a)_____mm Hg b)_____% c)___/___/___	6. If greater than 4 LPM is prescribed, enter results of most recent test taken on 4 LPM. This may be an (a) 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
Y N	7. Does the patient have dependent edema due to congestive heart failure?
Y N	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?
Y N	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) Supplier's charge and (3) Medicare Fee Schedule Allowance for each item, accessory and option. (See instructions on back.)

SECTION D Physician Attestation and Signature/Date

I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, 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 I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ___/___/___

Signature and Date Stamps Are Not Acceptable.

Form CMS-484 (09/05)

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