Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REPLACEMENT SCHEDULES FOR MEDICARE CONTINUOUS POSITIVE AIRWAY PRESSURE SUPPLIES

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EXECUTIVE SUMMARY: REPLACEMENT SCHEDULES FOR MEDICARE CONTINUOUS POSITIVE AIRWAY PRESSURE SUPPLIES
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WHY WE DID THIS STUDY

Since 2009, the Office of Inspector General has identified reducing waste in health care services as a top management challenge for the Department of Health and Human Services (HHS). In 2012, HHS's Centers for Medicare & Medicaid Services (CMS) found that beneficiaries receiving continuous positive airway pressure (CPAP) treatment for obstructive sleep apnea may have received more supplies (e.g., masks, tubing) than medically necessary; however, the quantities did not exceed the established replacement schedule. Providing more supplies than necessary may lead to wasteful spending.

HOW WE DID THIS STUDY

We requested CPAP replacement supply schedules in effect as of January 1, 2012, from 50 fee-for-service State Medicaid programs and from 4 fee-for-service Federal Employees Health Benefits (FEHB) plans. We compared the replacement schedules for 15 types of CPAP supplies with Medicare's schedules. Additionally, we collected recommended replacement schedules from five sleep disorder clinicians and four manufacturers.

WHAT WE FOUND

For supplies for which State Medicaid programs specified frequency schedules, 39 percent of frequencies were less than those under Medicare, and 51 percent equaled those under Medicare. Only 10 percent of frequencies exceeded those under Medicare. Additionally, many State Medicaid programs have either recently changed their schedules or have initiatives underway to do so. Two FEHB plans had no specific replacement schedules; the plans determined coverage on the basis of medical necessity. Sleep medicine clinicians emphasized the importance of proper mask fit, but research suggested that once proper mask fit is established, replacement of masks is less frequent than Medicare allows. Finally, manufacturers recommended specific replacement frequencies for only a few types of supplies, but those recommendations were often to replace those supplies on an as-needed basis and potentially less frequently than under Medicare's replacement schedule.

WHAT WE RECOMMEND

We recommend that CMS review the CPAP supply replacement schedule and revise the national coverage determination or request that the Durable Medical Equipment Medicare Administrative Contractors revise their local coverage determinations as appropriate. CMS did not concur with our recommendation. CMS stated that failure to consider noncompliance or the potential impact of supplier fraud or abuse would bias the estimate of a clinically appropriate refill rate. Although our report does not include this specific information, we continue to believe that our evidence is sufficient to warrant the recommendation that CMS review the supply replacement schedule and make revisions as appropriate.

TABLE OF CONTENTS

OBJECTIVE

To determine the extent to which the replacement schedule for continuous positive airway pressure (CPAP) supplies under Medicare's fee-for-service system differed from those of other health insurers and the recommendations of clinicians and CPAP machine manufacturers.

BACKGROUND

Since 2009, the Office of Inspector General (OIG) has identified reducing waste in health care services as a top management challenge for the Department of Health and Human Services (HHS).[1] In 2012, HHS's Centers for Medicare & Medicaid Services (CMS) found that beneficiaries may have received more CPAP supplies than medically necessary;[2] however, the quantities did not exceed the established replacement schedule. Providing more supplies than necessary may lead to wasteful spending.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003[3] required that Medicare replace the existing fee-schedule payment methodology for selected durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) with a competitive-bid process. The purpose of competitive bidding was to improve the effectiveness of Medicare's method of establishing DMEPOS payment amounts.[4] Although competitive bidding reduced the prices that Medicare paid for selected DMEPOS in selected areas, it did not change the frequency at which Medicare allows reimbursement for those items.

In April 2012, CMS released a report on competitive bidding for DMEPOS, including CPAP supplies. As part of the review, CMS staff telephoned beneficiaries who had claims for CPAP replacement supplies prior to the inception of the competitive bidding program, but no claims for supplies thereafter. The beneficiaries reported that they had more than enough supplies on hand, often multiple months' worth, and, therefore, did not need to obtain additional supplies after the competitive bidding program began. In its report, CMS concluded that this situation "suggests

[1] OIG, *Top Management and Performance Challenges*. Accessed at https://oig.hhs.gov/ on October 18, 2012.

[2] CMS, *Competitive Bidding Update—One Year Implementation Update*, p. 5, April 17, 2012. Accessed at http://www.cms.gov/ on April 27, 2012.

[3] P.L. 108-173 § 302(b).

[4] CMS, *Overview of the DMEPOS Competitive Bidding Program*. Accessed at http://www.dmecompetitivebid.com on November 1, 2012.

that beneficiaries received replacement supplies before they became medically necessary."[5]

CPAP

Positive airway pressure, commonly administered by a CPAP machine, is the most widely used method for treating obstructive sleep apnea (OSA). Individuals diagnosed with OSA experience physical blockages or obstructions in the airway during sleep, usually because the back of the tongue collapses against the soft palate and the soft palate collapses against the back of the throat. A CPAP machine works by gently blowing pressurized air through a tube attached to a mask worn by the user. The pressurized air keeps the user's throat open and acts as a sort of splint while the user sleeps.[6]

Studies of the effect of positive airway pressure therapy show that OSA patients who consistently use their machines feel better and, as a result of the reduction of episodes of apnea during sleep, encounter fewer complications of the condition.[7] However, the use of a CPAP machine is a form of continuous therapy for OSA patients and not a cure for OSA. Individuals will continue to use a CPAP machine indefinitely unless another intervention (e.g., weight loss) addresses the OSA.[8]

Because of the continuous use, a variety of CPAP supplies—such as masks, tubing, chinstraps, and filters—must occasionally be replaced, thus incurring recurring expenses. For example, the mask material tends to absorb oil from the skin and may become stiff, needing to be replaced. In addition, some CPAP models have nonwashable air filters that require periodic replacement.

Medicare Part B Coverage of CPAP Supplies

Medicare Part B covers durable medical equipment (DME) as well as supplies and services that are essential to the effective use of the equipment. Medicare initially covers the cost of a CPAP machine for up to 12 weeks if the beneficiary's OSA diagnosis is documented by a sleep

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[5] CMS, *Competitive Bidding Update—One Year Implementation Update*, p. 5, April 17, 2012. Accessed at http://www.cms.gov/ on April 27, 2012.

[6] American Sleep Apnea Association, *Positive Airway Pressure Therapy*. Accessed at http://sleepapnea.org/ on April 30, 2012.

[7] Ibid.

[8] Nigel McArdle et. al., "Long-term Use of CPAP Therapy for Sleep Apnea/Hypopnea Syndrome." *American Journal of Respiratory and Critical Care Medicine*, Vol. 159 No. 4, pp. 1108–1114, April 1, 1999. Accessed at http://171.66.122.149/content/159/4/1108.abstract on March 12, 2012.

study.[9] Medicare covers the CPAP machine after the initial 12-week period for those beneficiaries diagnosed with OSA who benefit from CPAP during the initial 12-week period.[10]

Through LCDs, each of the four DME MACs established identical CPAP supply replacement schedules.[11] For example, DME MACs will reimburse a supplier for a CPAP mask (A7034) every 3 months and a nondisposable filter (A7039) every 6 months. Medicare will not pay for items or services that exceed this replacement schedule because they would not be considered "reasonable and necessary."[12] Table 1 lists the Healthcare Common Procedure Coding System (HCPCS) codes, correlating descriptions of CPAP replacement supplies, and the DME MACs' determination of the maximum number of reasonable and necessary replacement of CPAP supplies.

[9] CMS, "Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)," *Medicare National Coverage Determinations Manual*, Pub. 100-03, § 240.4. Accessed at http://www.cms.gov/ on March 12, 2012. Medicare also provides limited coverage for CPAP machines for beneficiaries enrolled in certain clinical studies.

[10] Ibid. CMS may establish national coverage determinations (NCD) for DMEPOS. NCDs specify whether certain medical items, services, treatment procedures, or technologies are eligible for Medicare payment. When an NCD does not exist or when there is need for further definition, a local coverage determination (LCD) may be established by a CMS contractor. Through LCDs, each of the four Durable Medical Equipment Medicare Administrative Contractors (DME MAC) established minimum utilization criteria that must be met to establish that beneficiaries are benefiting from CPAP therapy. If the criteria are not met, continued coverage of a CPAP machine and related supplies will be denied as not reasonable and necessary. (See LCD numbers listed in footnote 11.)

[11] The four DME MACs and their respective LCD numbers for CPAP replacement supplies are CIGNA Government Services (L11518), National Government Services (L27230), National Heritage Insurance Company (L11504), and Noridian Administrative Services (L171).

[12] Social Security Act (SSA), § 1862(a)(1)(A).

Table 1: DME MACs' Determination of Reasonable and Necessary Replacement of CPAP Supplies

HCPCS Code	Description	Frequency
A4604	CPAP Tubing With Heating Element	1 per 3 months
A7027	Combination Oral/Nasal CPAP Mask	1 per 3 months
A7028	Replacement Oral Cushion for Oral/Nasal Mask	2 per 1 month
A7029	Replacement Nasal Pillows for Oral/Nasal Mask, One Pair	2 per 1 month
A7030	Full Face Mask	1 per 3 months
A7031	Full Face Mask Interface	1 per 1 month
A7032	Cushion for Nasal Mask Interface	2 per 1 month
A7033	Nasal Pillows	2 per 1 month
A7034	Nasal Interface	1 per 3 months
A7035	Headgear	1 per 6 months
A7036	Chinstrap	1 per 6 months
A7037	Tubing	1 per 3 months
A7038	Disposable Filter	2 per 1 month
A7039	Nondisposable Filter	1 per 6 months
A7046	Humidifier Water Chamber	1 per 6 months

Source: DME MAC LCDs: CIGNA Government Services (L11518) dated February 4, 2011; National Government Services (L27230) dated October 1, 2011; National Heritage Insurance Company (L11504) dated February 4, 2011; and Noridian Administrative Services (L171) dated October 1, 2011.

The LCDs were first issued in 1993. At that time, medical review staff at DME claims payment contractors contacted CPAP manufacturers and clinicians to ask questions about the length of time that supplies were expected to last. Supply frequencies were established on the basis of these contacts. With one exception (i.e., tubing), the replacement frequencies have remained the same for the past 20 years.

Related Report

A 2012 study of Veterans Healthcare Administration (VHA) patients with OSA receiving positive airway pressure therapy for more than 1 year found that CPAP supply refill rates were much greater in adherent patients

than in nonadherent patients.[13] Researchers selected a study population of patients receiving positive airway pressure therapy for more than 1 year because replacement rates, particularly for masks, can be more frequent during the first year of use. During the initial period of use, patients might need to try several masks to find the proper fit.[14] Researchers found that the rates at which patients replaced supplies were a good predictor of long-term adherence to positive airway pressure therapy.

METHODOLOGY

Scope

We limited our study to the replacement schedules in effect as of January 1, 2012, for the 15 types of CPAP supplies listed on DME MAC LCDs. To ensure equitable comparisons, we compared the supply replacement schedules and methods for establishing those schedules only to those of other fee-for-service health insurers. Of the 15 types of CPAP supplies, masks (A7027, A7030, and A7034) have the highest per-unit fee schedule reimbursement amounts under the Medicare fee schedule. The 2012 fee schedule amounts for the three types of CPAP masks ranged from $108.90 to $209.57 depending on the type of mask and geographic jurisdiction. In 2011, masks accounted for 48 percent of the total expenditures for CPAP supplies. Therefore, we calculated the effects of replacement schedule changes only for masks rather than for all 15 types of CPAP supplies.

We did not determine the validity of the diagnoses that led to the initial prescription for a CPAP machine, nor did we determine the medical necessity of the CPAP machine for the patients. Our review covered the replacement schedules and did not include the fee schedules or reimbursement rates paid by health insurers.

[13] Nimesh Patel, D.O.; Afshin Sam, M.D.; Alexandra Valentin, RRT; Stuart F. Quan, M.D; and Sairam Parthasarathy, M.D. "Refill Rates of Accessories for Positive Airway Pressure Therapy as a Surrogate Measure of Long-Term Adherence." *Journal of Clinical Sleep Medicine*, Vol. 8, No. 2, 2012, pp. 169–175. This study defined "adherence" using a modified version of the compliance criteria set forth in the LCDs of the four DME MACs. For three of the four DME MACs—CIGNA Government Services, National Government Services, and Noridian Administrative Services—"adherence" is defined as use of the machine for at least 4 hours per night on 70 percent of nights during a consecutive 30-day period anytime during the first 3 months of use. For the remaining DME MAC—National Heritage Insurance Company—"adherence" is defined as an average of 4 hours of use per 24-hour period on or after 61 days of initiation of CPAP therapy.

[14] National Institutes of Health, National Heart, Lung, and Blood Institute. Accessed at http://www.nhlbi.nih.gov on February 11, 2013.

Data Collection

We requested CPAP replacement supply schedules in effect as of January 1, 2012, from 50 fee-for-service State Medicaid programs and from 4 fee-for-service Federal Employees Health Benefits (FEHB) plans.[15] These four FEHB plans provide coverage to 93 percent of fee-for-service FEHB enrollees. We surveyed each of the State Medicaid programs and the selected FEHB plans to ascertain how they formulated their supply replacement schedules.

We also collected recommended replacement schedules from clinicians and manufacturers. To obtain clinician recommendations, we contacted the director of the National Center on Sleep Disorders Research in the National Heart, Lung, and Blood Institute's Division of Lung Diseases at the National Institutes of Health. The director provided the contact information for five sleep disorder clinicians who also conduct sleep apnea research in academic settings. We conducted structured interviews with these five clinicians to obtain their recommendations. Additionally, we surveyed four manufacturers of CPAP machines to determine their recommended replacement supply schedules.[16]

Data Analysis

Replacement Schedule Comparisons. Medicare, State Medicaid programs, and FEHB plans state the frequencies of replacement supplies in varying timeframes. For example, Medicare states the replacement frequency for masks as 1 per 3 months and the replacement frequency for disposable filters as 2 per 1 month. To perform equitable comparisons, we converted all frequency schedules to annual frequencies (e.g., 4 masks per year, 24 disposable filters per year), although health insurers reimburse for supplies according to the stated frequency.

Effects of Replacement Schedule Changes. To calculate the effects of potential changes to replacement schedules on the Medicare program, we used the population of Medicare claims from 2011 for three types of CPAP masks: A7027, A7030, and A7034. To identify mask claims for beneficiaries using machines for more than 1 year, we excluded masks for beneficiaries who also had claims for positive airway pressure machines (i.e., E0470, E0471, E0472, and E0601) during 2010 and 2011. Using this approach enabled us to better identify the claims for masks that were

[15] Staff from the Tennessee Medicaid program stated that 100 percent of recipients are enrolled in managed care plans; therefore, Tennessee does not pay for CPAP supplies on a fee-for-service basis. We did not include the Tennessee Medicaid program in our data collection but included the District of Columbia, for a total of 50 State Medicaid programs.

[16] The four manufacturers are DeVilbiss Healthcare, Fisher & Paykel, Philips/Respironics, and ResMed.

replacements versus claims for masks that beneficiaries received to ensure proper fit. Table 2 shows the number of beneficiaries with claims for masks in 2011 who did not have claims for machines during 2010 and 2011.

Table 2: 2011 Mask Claims for Beneficiaries Using CPAP Machines for More Than 1 Year

Number of Masks	A7027		A7030		A7034	
	Number of Beneficiaries	Allowed Dollars	Number of Beneficiaries	Allowed Dollars	Number of Beneficiaries	Allowed Dollars
1	3,074	$589,420	92,075	$15,478,300	179,456	$18,752,549
2	857	$328,486	41,072	$13,831,501	80,697	$16,881,285
3	354	$203,872	20,681	$10,464,637	38,331	$12,036,781
4	139	$106,620	8,510	$5,749,508	16,126	$6,765,351
5	1	$941	245	$207,358	340	$176,731
6	N/A	N/A	54	$55,258	58	$35,273
7	N/A	N/A	13	$15,220	26	$19,356
8	N/A	N/A	8	$10,915	8	$6,806
9	N/A	N/A	1	$1,535	3	$2,871
Total	4,425	$1,229,339	162,659	$45,814,232	315,045	$54,677,003

Note: Although DME MAC LCDs have determined that one mask per 3 months is the maximum reasonable and necessary quantity, Medicare beneficiaries can appeal for the reimbursement of additional claims.

Dollar amounts are rounded to the nearest $1.

Source: Medicare National Claims History File, 2012.

Although Medicare allows up to four masks per year, the majority of beneficiaries received only one or two. Not all beneficiaries replaced supplies at the coverage policy's maximum amount. It is expected that beneficiaries whose clinical conditions do not require the maximum quantities should receive only the quantities that they need. Medicare does not pay for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.[17]

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

[17] SSA, § 1862(a)(1)(A).

FINDINGS

Medicare, other health insurers, sleep medicine clinicians, and CPAP manufacturers differ widely on replacement frequencies for supplies

Seventy-four percent of State Medicaid programs had replacement schedules for CPAP supplies; 39 percent of these schedules permitted replacement less frequently than did Medicare

Thirty-seven of 50 State Medicaid programs (74 percent) reported that they had replacement schedules for CPAP supplies in effect as of January 1, 2012. Of the 13 State Medicaid programs that reported having no replacement schedules, 9 programs reported that supplies were replaced on the basis of medical necessity.[18] The remaining four programs (Arkansas, Florida, New Jersey, and Rhode Island) reported that the monthly reimbursement for the rental of the CPAP machine included all necessary supplies. Because these four States did not use replacement schedules, we did not further explore the costs associated with continuously renting this equipment.

For the 37 State Medicaid programs that had replacement supply schedules, we compared the frequency of replacement for each of the 15 types of supplies with that of Medicare.[19] For those supplies for which State Medicaid programs specified replacement frequency schedules, 39 percent of frequencies were less than those under Medicare, 51 percent equaled those under Medicare, and 10 percent exceeded those under Medicare. Table 3 shows the range of State Medicaid program replacement frequencies and Medicare's frequencies for all types of supplies reviewed.

[18] State Medicaid programs did not provide a specific definition of "medical necessity."

[19] Not all of the State Medicaid programs had replacement frequencies for each of the 15 types of supplies.

Table 3: Comparison of State Medicaid Programs' and Medicare's Replacement Schedules for CPAP Supplies

HCPCS Code	Description	Annual Frequency of Replacement		
		Lowest State Medicaid Program Frequency	Highest State Medicaid Program Frequency	Medicare Frequency
A4604	CPAP Tubing With Heating Element	1	24	4
A7027	Combination Oral/Nasal CPAP Mask	1	12	4
A7028	Replacement Oral Cushion for Oral/Nasal Mask	1	24	24
A7029	Replacement Nasal Pillows for Oral/Nasal Mask, One Pair	1	24	24
A7030	Full Face Mask	1 per 5 years	12	4
A7031	Full Face Mask Interface	1	12	12
A7032	Cushion for Nasal Mask Interface	1	24	24
A7033	Nasal Pillows	1	24	24
A7034	Nasal Interface	1 per 5 years	24	4
A7035	Headgear	1	12	2
A7036	Chinstrap	1	12	2
A7037	Tubing	1	12	4
A7038	Disposable Filter	4	72	24
A7039	Nondisposable Filter	1	12	2
A7046	Humidifier Water Chamber	1 per 3 years	12	2

Note: We converted reported frequencies to annual frequencies.
Source: OIG analysis of State Medicaid program survey responses, 2012.

The replacement frequencies for all 37 State Medicaid programs can be found in Appendix A.

Many State Medicaid Programs Have Changed or Have Initiatives Underway To Change CPAP Supply Replacement Schedules. Medicare's CPAP supply replacement frequency schedule has remained largely the same for the past 20 years; however, many State Medicaid programs have either recently changed their schedules or have initiatives underway to do so. Eight State Medicaid programs made changes to their schedules between 2009 and 2011. For example, in October 2009, the New York Medicaid program changed the allowed replacement frequency for nondisposable filters without prior approval from three filters every 2 months to two filters every 6 months.

Another 10 State Medicaid programs reported that they had initiatives underway to change the replacement schedules for CPAP supplies. For example, four States were reviewing their policies for CPAP supplies. Another three States will address CPAP supply replacement frequencies in conjunction with the implementation of new Medicaid management information systems.

Medicare Expenditures for Masks Could Be Less If the Replacement Schedule Were Changed To Match Selected State Medicaid Program Schedules. We calculated the effects of Medicare expenditures for CPAP masks if Medicare changed its schedule to those of selected State Medicaid programs. Two State Medicaid programs (Minnesota and Virginia) used replacement schedules that allowed one mask replacement per 4 months. Six State Medicaid programs used replacement schedules that allowed one mask replacement per 6 months.[20] Appendix B shows the potential reductions in Medicare expenditures if Medicare changed its replacement schedule for masks. We note that, regardless of the number of mask replacements allowed, an important aspect of cost control is to ensure that beneficiaries receive only the quantities sufficient to meet the needs of their clinical conditions.

Two FEHB plans followed Medicare's replacement schedule and two plans had no specific schedules

Of the four FEHB plans that we surveyed, two plans reported that they followed Medicare's replacement schedule for CPAP supplies and the other two plans had not established specific schedules. The two plans that followed Medicare's schedule further stated that they would consider exceptions for circumstances such as improperly fitted or worn supplies in allowing CPAP supplies in greater quantity or frequency. The other two plans stated that they did not limit the frequency of replacement of supplies; instead, the plans determined coverage on the basis of medical necessity.[21]

Clinicians emphasized the importance of proper mask fit; clinical research suggested that once proper mask fit is established, replacement is less frequent than Medicare allows

All five of the sleep disorder medicine clinicians with whom we spoke emphasized that proper mask fit is an important factor in achieving patient adherence with CPAP therapy. During the first year, and particularly

[20] The six State Medicaid programs are Alabama, Georgia, Hawaii, Missouri, North Carolina, and North Dakota. Alabama and Hawaii specified a replacement frequency of two masks per year for only two of the three types of masks (i.e., A7030 and A7034).

[21] FEHB plans did not provide a specific definition of "medical necessity."

within the initial 3-month period of use, patients may need to try several types or brands of masks to find the best fit.

One clinician characterized Medicare's CPAP supply replacement schedule as "generous." Another clinician recommended that replacing masks once every 4 months (3 per year) was sufficient. Finally, two clinicians commented that the material used in some supplies (e.g., tubing) is becoming more durable, necessitating less frequent replacement.

The fifth clinician conducted research on VHA patients receiving positive airway pressure therapy for more than 1 year. This clinician found that supply replacement rates were much greater in adherent patients than in nonadherent patients.[22] The median refill rate of all supplies combined (e.g., masks, tubing, filters) for adherent patients was 1.5 items per year. The median replacement rate for masks alone was 0.67 per year for adherent patients—less than 1 mask per year (as compared to Medicare's allowed frequency of 1 per 3 months). We note that VHA does not have a replacement schedule for CPAP supplies. Instead, replacements are provided upon patient request.

Manufacturers recommended specific replacement frequencies for only a few types of supplies

Three of the four CPAP machine manufacturers that we surveyed recommended specific replacement frequencies for certain supplies. In those cases, manufacturers' recommended frequencies were equal to or less frequent than those under Medicare's schedule. Most commonly, manufacturers had replacement frequency recommendations for filters (i.e., A7038, A7039). However, instead of specific frequency recommendations, each of the manufacturers commented that the frequency of replacement was variable and was based on individual use, method and frequency of cleaning, and the environment in which the CPAP equipment was used. For example, one manufacturer recommended replacing a mask if it "became weakened or cracked." Another manufacturer that had no specific recommendation for the frequency of replacing filters commented that a filter should be replaced "if it shows signs of dirt or damage."

[22] Nimesh Patel, D.O.; Afshin Sam, M.D.; Alexandra Valentin, RRT; Stuart F. Quan, M.D; and Sairam Parthasarathy, M.D. "Refill Rates of Accessories for Positive Airway Pressure Therapy as a Surrogate Measure of Long-Term Adherence." *Journal of Clinical Sleep Medicine*, Vol. 8, No. 2, 2012, pp. 169-175.

CONCLUSION AND RECOMMENDATION

Medicare, other health care insurers, sleep medicine clinicians, and CPAP manufacturers differ widely on replacement frequencies for supplies. For supplies for which State Medicaid programs specified replacement frequency schedules, 39 percent of frequencies were less than those under Medicare and 51 percent equaled those under Medicare. Only 10 percent exceeded those of Medicare. Additionally, many State Medicaid programs have either recently changed their schedules or have initiatives underway to do so. Two FEHB plans had no specific replacement schedules; the plans determined coverage on the basis of medical necessity. Sleep medicine clinicians emphasized the importance of proper mask fit, but research suggested that once proper mask fit is established, replacement of masks is less frequent than Medicare allows. Finally, manufacturers recommended specific replacement frequencies for only a few types of supplies, but those recommendations were often to replace those supplies on an as-needed basis and potentially less frequently than Medicare's replacement schedule.

CPAP supplies are included in one product category of CMS's competitive-bid process, which began for limited categories of DMEPOS in 2011. First year savings for this category totaled over $19 million. However, competitive bidding does not address replacement schedules, and Medicare's CPAP supply replacement frequency schedule has remained largely the same for the past 20 years.

We recommend that CMS:

Review the CPAP Supply Replacement Schedule and Revise the National Coverage Determination for CPAP Therapy for OSA or Request That the DME MACs Revise Their LCDs as Appropriate

We present evidence from State Medicaid programs and clinicians that supports less frequent replacement than what Medicare allows. We also present suggestions from respondents to replace supplies on an as-needed basis. CMS could consider allowing a more generous schedule for CPAP machine users during the first year of use and a less frequent replacement schedule for established users. If CMS deems revision of the CPAP supply replacement schedule to be warranted, it should revise its NCD to include an appropriate CPAP supply replacement schedule and ensure that the DME MACs make corresponding changes to their LCDs. Alternatively, CMS could request that the DME MACs revise their LCDs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur with our recommendation. CMS stated that additional information specific to CPAP use among adherent beneficiaries as well as that related to Medicare suppliers should be explored before any recommendations are provided. CMS also stated that failure to consider noncompliance or the potential impact of supplier fraud or abuse would bias the estimate of a clinically appropriate refill rate. Although our report does not include this specific information, we continue to believe that our evidence is sufficient to warrant the recommendation that CMS review the supply replacement schedule and make revisions as appropriate. We agree that CMS will likely set more accurate rates if the additional information referenced above is obtained.

We did not make any changes to the report based on CMS's comments. The full text of CMS's comments is provided in Appendix C.

APPENDIX A

State Medicaid Program Replacement Schedules for Continuous Positive Airway Pressure Supplies

State	Annual Frequency of Replacement						
	A4604	A7027	A7028	A7029	A7030	A7031	A7032
Alabama	N/A	N/A	N/A	N/A	2	2	2
California	2	1	12	24	1	1	12
Connecticut	12	12	24	24	12	12	24
Delaware	4	N/A	N/A	N/A	2	2	24
District of Columbia	4	4	4	4	4	4	4
Georgia	N/A	2	12	12	2	1	12
Hawaii	24	N/A	N/A	N/A	2	2	2
Idaho	4	4	24	24	4	12	24
Illinois	2	2	2	3	2	1	12
Iowa	4	4	24	24	4	12	24
Kansas	1	1	1	1	1	1	1
Louisiana	4	N/A	N/A	N/A	4	12	24
Maine	12	4	24	24	4	12	24
Maryland	1	4	24	24	12	12	24
Massachusetts	N/A	4	6	6	4	12	24
Michigan	N/A	1	1	1	1	1	1
Minnesota	4	3	12	12	3	12	12
Mississippi	N/A	N/A	N/A	N/A	4	4	12
Missouri	N/A	2	2	6	2	2	2
Montana	4	4	24	24	4	12	24
Nebraska	N/A	4	24	N/A	4	12	24
Nevada	4	4	24	24	4	12	24
New Mexico	4	4	24	24	4	4	24
New York	N/A	2	2	2	1 per 5 years	2	2
North Carolina	N/A	2	2	2	2	2	2
North Dakota	12	2	24	24	2	12	24
Ohio	N/A	N/A	N/A	N/A	1	N/A	2
Oklahoma	N/A	1	1	1	1	1	1
Oregon	4	4	24	24	4	12	24
Pennsylvania	4	4	24	24	2	4	12
South Carolina	2	1	1	1	2	2	2
Texas	N/A	4	12	24	4	12	24
Utah	N/A	N/A	1	1	1	1	1
Vermont	4	4	24	12	4	12	24
Virginia	12	3	3	3	3	3	3
Washington	2	N/A	N/A	N/A	2	4	2
West Virginia	12	N/A	N/A	N/A	2	2	24

Note: We converted reported frequencies to annual frequencies. "N/A" indicates that no replacement frequency was reported for that supply. State Medicaid programs may make exceptions to these replacement schedules based on medical necessity.

continued on next page

State Medicaid Program Replacement Schedules for Continuous Positive Airway Pressure Supplies (Continued)

State	Annual Frequency of Replacement							
	A7033	A7034	A7035	A7036	A7037	A7038	A7039	A7046
Alabama	2	2	2	2	1	12	2	2
California	24	2	2	2	2	24	2	2
Connecticut	24	12	12	12	12	24	12	12
Delaware	24	4	2	2	4	12	N/A	N/A
District of Columbia	4	4	4	4	4	4	4	4
Georgia	12	2	2	2	12	12	2	1 per 3 years
Hawaii	4	2	1	1	2	4	1	2
Idaho	24	4	2	2	4	12	2	2
Illinois	12	4	2	2	2	24	2	3
Iowa	24	4	2	2	4	24	2	2
Kansas	N/A	N/A	1	1	1	N/A	1	1
Louisiana	24	4	2	2	12	24	2	2
Maine	24	24	2	2	12	24	2	12
Maryland	24	4	2	2	4	24	12	2
Massachusetts	24	4	2	2	4	6	2	2
Michigan	1	1	1	1	1	18	N/A	2
Minnesota	12	3	3	2	12	36	3	4
Mississippi	12	4	2	2	12	24	2	N/A
Missouri	6	2	2	2	2	24	2	N/A
Montana	24	4	2	2	4	24	2	2
Nebraska	24	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Nevada	24	4	2	2	4	24	2	2
New Mexico	24	4	4	2	4	24	12	2
New York	2	1 per 5 years	2	2	2	4	4	N/A
North Carolina	2	2	2	1	2	12	6	N/A
North Dakota	24	2	2	2	12	24	2	2
Ohio	2	1	1	2	1	12	4	N/A
Oklahoma	1	1	1	1	1	24	2	2
Oregon	24	4	2	2	4	24	2	2
Pennsylvania	12	12	12	12	4	72	12	2
South Carolina	2	2	2	2	2	5	2	2
Texas	24	4	2	N/A	12	24	2	N/A
Utah	1	1	2	2	2	4	1	N/A
Vermont	12	4	2	2	4	24	2	2
Virginia	3	3	3	3	3	12	12	12
Washington	2	2	2	2	2	12	2	2
West Virginia	24	4	2	2	12	24	2	1

Source: Office of Inspector General analysis of Medicaid program survey responses, 2012.

APPENDIX B

Decreases in Medicare Expenditures for Masks If the Replacement Schedule Were Changed

If Medicare reduced the frequency of mask replacement from one per 3 months to one per 6 months, expenditures would decrease by $14,212,244, or 14 percent. If Medicare reduced the frequency of mask replacement to one per 4 months, expenditures would decrease by $3,388,465, or 3 percent. The savings calculations assume that all beneficiaries who received masks at the current maximum frequency will decrease to the new maximum frequency and that there is no change for beneficiaries that received fewer masks than the current maximum frequency.

Mask Type	Impact If Replacement Schedule Changed to Two Masks Per Year		Impact If Replacement Schedule Changed to Three Masks Per Year	
	Number of Beneficiaries Affected	Decrease in Allowed Dollars	Number of Beneficiaries Affected	Decrease in Allowed Dollars
A7027	494	$121,816	140	$27,004
A7030	29,512	$6,544,549	8,831	$1,564,440
A7034	54,892	$7,545,879	16,561	$1,797,021
Total	84,898 (18%)	$14,212,244 (14%)	25,532 (5%)	$3,388,465 (3%)

Note: Dollar amounts are rounded to the nearest $1.
Source: Medicare National Claims History File, 2012.

APPENDIX C
Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR 2 6 2013

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Replacement Schedules for Medicare Continuous Positive Airway Pressure (CPAP) Supplies" (OEI-07-12-00250)

Thank you for the opportunity to review and comment on the above-subject draft report. OIG is trying to determine the extent to which the replacement schedule for CPAP supplies under Medicare's fee-for-service system differed from those of other health insurers and the recommendations of clinicians and CPAP machine manufacturers. OIG found that supplies for which state Medicaid programs specified frequency schedules, 39 percent had replacement frequencies that were less frequent than those under Medicare and 51 percent had replacement frequencies equal to those under Medicare. Only 10 percent of supply replacement frequencies were more frequent than those under Medicare. Additionally, many state Medicaid programs have either recently changed their CPAP supply replacement schedules or have initiatives underway to do so. Two Federal Employees Health Benefits plans had no specific replacement schedule; the plans determined coverage on the basis of medical necessity. Sleep medicine clinicians emphasized the importance of proper mask fit, but once mask fit is established, research indicated less frequent replacement of masks than Medicare allows. Finally, OIG found that manufacturers recommended specific replacement frequencies for only a few types of supplies, but those recommendations were often to replace those supplies on an as-needed basis and potentially less frequently than under Medicare's replacement schedule.

OIG recommendation and CMS response to the recommendation is discussed below.

OIG Recommendation

The OIG recommends that CMS Review the CPAP Supply Replacement Schedule and Revise the National Coverage Determination for CPAP Therapy for OSA or Request That the DME MACs Revise Their LCDs as Appropriate.

CMS Response

The CMS does not concur with the OIG recommendation. In order to determine if CPAP supply refill frequency can be reduced, an analysis of Medicare beneficiary CPAP use similar to that performed in the Veterans Health Administration study is needed (i.e., comparing actual CPAP

Agency Comments (Continued)

usage data with numbers of equipment refills obtained). A study of this nature would support the determination of refill rates for patients who adhere to therapy, rather than confounding the analysis by pooling refill rates across both adherent and non-adherent beneficiaries. Coverage policy of replacement CPAP supplies would be better informed by data derived from patients who adhere to their prescribed CPAP treatments. Failure to take into consideration non-compliance or the potential impact of supplier fraud /abuse would bias the estimate of the clinically appropriate refill rate. Therefore we believe additional information on our specific population as well as that related to Medicare suppliers should be explored before any recommendations are provided.

The CMS thanks the OIG for the opportunity to review and comment on this report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Brian T. Whitley, Acting Regional Inspector General for Evaluation and Inspections in the Kansas City regional office.

Tricia Fields served as the team leader for this study. Other Office of Evaluation and Inspections staff from the Kansas City regional office who conducted the study include Jordan Clementi and Brian Pattison. Central office staff who provided support include Clarence Arnold, Scott Manley, and Christine Moritz.

Office of Inspector General

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