

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**BENEFICIARY UTILIZATION OF
ALBUTEROL AND
LEVALBUTEROL UNDER
MEDICARE PART B**



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OBJECTIVE

To determine whether shifts in utilization patterns for albuterol and levalbuterol from January 1, 2003, through December 31, 2007, coincided with changes in Medicare Part B payment and coding policy.

BACKGROUND

Two inhalation drugs, albuterol and levalbuterol, are bronchodilators used primarily to treat asthma and chronic obstructive pulmonary disease. Some clinical studies suggest that levalbuterol has a greater efficacy and fewer side effects than albuterol; however, other trials have failed to detect any clinical advantage.

In 2003 and 2004, albuterol and levalbuterol were included in the same payment code and had the same Medicare payment amount, based on the median average wholesale price (AWP) of all versions of both drugs. Effective January 1, 2005, the Centers for Medicare & Medicaid Services (CMS) established separate payment codes and separate payment amounts for the drugs. At the same time, under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare reimbursement for an inhalation drug was set at 106 percent of the drug's average sales price (ASP). These changes increased the payment amount for levalbuterol from \$0.39 to \$1.28 per half milligram (mg), but decreased the payment amount for albuterol from \$0.39 to \$0.07 per mg in the first quarter of 2005 (for treatment purposes, 1 mg of albuterol is generally equivalent to 0.5 mg of levalbuterol).

Effective July 1, 2007, CMS recombined albuterol and levalbuterol into a single code, resulting in a Medicare payment amount of \$0.53 per mg of albuterol and per 0.5 mg of levalbuterol. As of April 1, 2008, CMS again reestablished separate payment codes and payment amounts for these two drugs (\$0.28 per 0.5 mg of levalbuterol and \$0.04 per mg of albuterol).

We surveyed the suppliers and physicians for 312 beneficiaries who had albuterol and/or levalbuterol claims between January 1, 2003, and December 31, 2007 (response rate of 96 percent for suppliers and 60 percent for physicians). Based on supplier responses, we calculated the percentage of beneficiaries who were changed to albuterol from levalbuterol and vice versa. To estimate the impact of changing between the two drugs on supplier reimbursement, we compared

Medicare's quarterly payment amounts for albuterol and levalbuterol to the estimated supplier acquisition cost (based on manufacturer-reported ASP). Using physician responses, we also determined reasons why changes occurred.

FINDINGS

Shifts in utilization patterns for albuterol and levalbuterol coincided with changes in payment and coding. In 2003 and 2004, Medicare reimbursement favored albuterol (from a supplier's reimbursement perspective) and nearly all beneficiaries (97 percent) received that drug. Specifically, in the fourth quarter of 2004, Medicare paid suppliers an average of almost five times more than their cost for albuterol, but significantly less than their cost for levalbuterol.

As a result of payment and coding changes that took effect on January 1, 2005, reimbursement became much more favorable for levalbuterol. We estimate that during the initial quarter after the coding and reimbursement change, suppliers were being reimbursed roughly at cost for albuterol, but 68 percent above cost for levalbuterol. Twenty-five percent of beneficiaries who were on albuterol in 2004 were changed to levalbuterol between January 1, 2005, and June 30, 2007.

As of July 1, 2007, CMS calculated one payment amount for albuterol and levalbuterol, which was based on the volume-weighted ASP for both drugs. As a result, suppliers were being reimbursed at almost 10 times their cost for albuterol, but roughly half their cost for levalbuterol. After this payment and coding change, two-thirds of the beneficiaries in our sample who received levalbuterol as of June 2007 were changed to albuterol.

Despite the move to ASP, average per-beneficiary spending on albuterol and levalbuterol actually increased above pre-MMA levels.

In the first half of 2003, because almost all of the beneficiaries (97 percent) were receiving albuterol rather than levalbuterol, the former accounted for the vast majority of spending during this time. The change to an ASP-based reimbursement system in January 2005 lowered the Medicare payment amount for albuterol by 83 percent. However, because utilization began slowly shifting to levalbuterol, overall per-beneficiary spending did not decline proportionally.

As the number of beneficiaries shifting to levalbuterol increased, so did the average spending per beneficiary. Between January 1 and June 30, 2007, when more than a quarter of beneficiaries were receiving

levalbuterol, Medicare paid an average of \$600 per beneficiary for both albuterol and levalbuterol, or \$94 more per beneficiary than in the first half of 2003.

Physicians in our sample typically cited clinical reasons for changing beneficiaries from albuterol to levalbuterol, but financial reasons for changing in the opposite direction. For 64 percent of beneficiaries in our sample who were changed from albuterol to levalbuterol between January 1, 2005, and June 30, 2007 (i.e., when levalbuterol became the more favorable drug from a reimbursement perspective), physicians reported that the changes occurred because of clinical reasons. During this same period, physicians for just 8 percent of beneficiaries in our sample cited financial reasons for the change to levalbuterol.

However, for 58 percent of beneficiaries in our sample who changed from levalbuterol to albuterol after July 1, 2007 (i.e., when albuterol became the more favorable drug from a reimbursement perspective), physicians reported that the prescriptions were changed because of financial concerns.

CONCLUSION

Between January 2005 and June 2007, when Medicare reimbursement shifted to favor the more expensive levalbuterol, one-quarter of the beneficiaries were changed from albuterol to the costlier product. Although a number of physicians cited clinical reasons for changing prescriptions, reimbursement considerations may have also played a role—especially given that some changes appear to have been completed by the suppliers without the physicians' knowledge and that the majority of the beneficiaries remained on albuterol despite the large differences in payment levels.

As a result of the July 1, 2007, payment and coding changes, most suppliers may have been losing money by providing levalbuterol, and at that time, many beneficiaries were changed back to albuterol, even though in some cases (according to physicians) albuterol had initially caused side effects. At this same time, however, the payment situation not only created a disincentive for levalbuterol, but also caused albuterol to be reimbursed at more than 10 times its cost.

As of April 1, 2008, CMS implemented a provision of the Medicare, Medicaid, and SCHIP Extension Act of 2007 that once again lowered albuterol reimbursement so that payment more accurately reflected

acquisition cost. However, the same provision prevented CMS from addressing any underpayment for levalbuterol.

When Congress and CMS make coding and reimbursement decisions, it is important they take into consideration that the new policies may affect what drug a beneficiary is prescribed. In some cases, this may limit access to a potentially more effective product; in others, utilization could be driven toward a more expensive product that offers no clinical advantage. In future studies, the Office of Inspector General will continue to monitor the utilization of and payment for these and other drugs, with the goal of identifying inappropriate Medicare payments.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS stated that the agency is aware of the impact that changes in payment methodologies can have on access to prescription drugs. However, CMS noted that in the case of albuterol and levalbuterol, changes to coding and pricing were not discretionary but instead were made to comply with legislative mandates. CMS stated that the agency has monitored and will continue to monitor spending and utilization for both drugs to help ensure price stability and access while fulfilling legal mandates.

In its technical comments, CMS noted two areas for further OIG investigation: (1) cases in which physicians were reportedly unaware of the medication changes; and (2) the clinical rationales for changing medications, including whether reports of clinical complications truly reflect actual complications. OIG will review cases in which prescription changes occurred without the physicians' knowledge to determine whether further investigation is warranted; however, OIG does not believe further investigation on physician rationales for prescription changes is necessary. We did not make any changes to the report based on CMS's comments.

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OBJECTIVE

To determine whether shifts in utilization patterns for albuterol and levalbuterol from January 1, 2003, through December 31, 2007, coincided with changes in Medicare Part B payment and coding policy.

BACKGROUND

Medicare Part B Coverage of Inhalation Drugs

Although Medicare Part D covers most outpatient prescription drugs, inhalation drugs are covered under Part B when administered in the home through a nebulizer.¹ A nebulizer is a type of durable medical equipment (DME) item that is provided to Medicare beneficiaries by DME suppliers. DME suppliers also provide inhalation drugs, which are covered under Part B as a supply necessary for the nebulizer to perform its function. Physicians typically prescribe inhalation drugs to treat and prevent symptoms associated with lung diseases, such as asthma and chronic obstructive pulmonary disorder. Long-term use is often required because inhalation drugs treat incurable and chronic diseases.

Two inhalation drugs, albuterol and levalbuterol, are bronchodilators used primarily to treat asthma and chronic obstructive pulmonary disease. The drugs essentially have the same chemical composition, except that levalbuterol contains only one of the two albuterol isomers. Some clinical studies suggest that because it lacks this isomer, levalbuterol has greater efficacy and produces fewer side effects than albuterol. However, other trials have failed to detect any clinical advantage of levalbuterol over albuterol.² Levalbuterol (brand name Xopenex) is a single-source drug manufactured by Sepracor and has no

¹ Medicare Part D covers inhalation drugs that (1) are not administered through a nebulizer, such as those delivered through a metered-dose inhaler; or (2) are administered through a nebulizer, but are not used in a patient's home (e.g., used in a hospital or skilled nursing facility by a beneficiary who does not have Part A coverage, who has exhausted his or her Part A coverage, or whose stay is noncovered). Hereinafter, all references to inhalation drugs in this report refer to inhalation drugs covered under Part B, i.e., administered in the home through a nebulizer.

² National Heart, Lung, and Blood Institute, National Asthma Education and Prevention Program, "Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma." Published on August 28, 2007. Available online at <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>. Accessed on January 4, 2008.

available generic versions. Albuterol is a multiple-source drug with generic versions available from numerous manufacturers.

The Centers for Medicare & Medicaid Services (CMS) contracts with four geographically defined DME Medicare Administrative Contractors (MAC) to process and pay for DME claims, including those for inhalation drugs.³ For Medicare to pay for an inhalation drug, the DME supplier must have a signed prescription from the treating physician and the physician's identification number must be listed on the submitted claim form. Generally, Medicare will pay 80 percent of the authorized reimbursement amount to the DME supplier providing the inhalation drug; the beneficiary is responsible for the remaining 20 percent in the form of coinsurance.

When a supplier submits a claim for reimbursement, the drug dispensed is identified on the claim using codes established by CMS as part of the Healthcare Common Procedure Coding System (HCPCS). The HCPCS codes provide a standardized system for describing the specific items and services provided in the delivery of health care. In the case of prescription drugs, each HCPCS code defines the drug name and dosage size but does not specify manufacturer or package size information.⁴

Medicare Part B Payment Methodology for Inhalation Drugs

Medicare's payment methodology for inhalation drugs administered through a nebulizer has undergone significant changes over the past 5 years, with the intent of making Medicare payments more reflective of acquisition costs. Pursuant to section 1842(o) of the Social Security Act (the Act), as amended by section 4556 of the Balanced Budget Act of 1997, P.L. No. 105-33, payment for inhalation drugs furnished on or after January 1, 1998, was set at 95 percent of the drug's average wholesale price (AWP). However, reports by the Government

³ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 (MMA), included provisions that required CMS to implement competitive procedures to replace DME regional carriers with DME MACs. In 2006, CMS competitively selected four DME MACs and began to transition claims administration activities from DME regional carriers to DME MACs. As of June 1, 2007, the four DME MACs awarded contracts were the National Heritage Insurance Company for Jurisdiction A; AdminaStar Federal, Inc., for Jurisdiction B; CIGNA Government Service, LLC, for Jurisdiction C; and Noridian Administrative Services for Jurisdiction D.

⁴ Typically, HCPCS codes correspond to a single drug distributed by one or more manufacturers. However, in some cases, HCPCS codes may represent several different drugs.

Accountability Office (GAO)⁵ and the Office of Inspector General (OIG) consistently demonstrated that suppliers could obtain drugs well below the Medicare payment amount under the AWP method. OIG issued several reports that focused specifically on the high-volume inhalation drug albuterol.⁶ Based in part on this work, sections 303(b)(2) and 305(a) of the MMA, P.L. No. 108-173, lowered the Medicare payment to 80 percent of AWP for some of the most commonly dispensed inhalation drugs, such as albuterol, in 2004.⁷ Other inhalation drugs were reimbursed at 85 percent of AWP.⁸

For 2005 and subsequent years, sections 303(c)(1) and 305(a) of the MMA changed the basis of payment for inhalation drugs (and most other Part B prescription drugs as well) to 106 percent of the volume-weighted average sales price (ASP).⁹ Section 1847A(c) of the Act, as added by the MMA, generally defines ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. CMS calculates a volume-weighted ASP for each covered HCPCS code by using an equation that involves manufacturer-reported ASP data, the volume of sales reported by the manufacturers, and the number of billing units in the national drug code determined by CMS.

Dispensing fees. In addition to paying the cost of the drug itself, Medicare also pays a separate dispensing fee for inhalation drugs under the DME benefit. Dispensing fees are intended to cover any reasonable pharmacy costs associated with distributing the drug, but do not include administrative fees. Prior to 2005, Medicare paid a monthly \$5 fee to the supplier each time an inhalation drug was dispensed.¹⁰ In 2005, Medicare raised the dispensing fee to \$57 for a 30-day supply or \$80 for a 90-day supply of inhalation drugs.¹¹ According to CMS,

⁵ GAO, "Payments for Covered Outpatient Drugs Exceed Providers' Cost," GAO-01-1118 (September 21, 2001).

⁶ For example, see "Excessive Medicare Reimbursement for Albuterol" (OEI-03-01-00410), March 2002.

⁷ Sections 1842(o)(1)(G)(i) and 1842(o)(4)(B), (C), and (D) of the Act.

⁸ Section 1842(o)(4)(A) of the Act.

⁹ Sections 1842(o)(1)(G)(ii) and 1847A of the Act.

¹⁰ CMS Press Release, "Appropriate Payments, High-Quality Care for Beneficiaries Using Inhalation Drugs." November 2, 2005.

¹¹ 69 Fed. Reg. 66236, 66425 (Nov. 15, 2004) (codifying earlier version of 42 CFR § 414.1001(c) and (d)).

because of the “overall reduction in payment for inhalation drugs,” the dispensing fee was increased because the agency was “concerned about beneficiary access to these drugs.”¹² Effective January 1, 2006, Medicare began paying \$57 for the first time a beneficiary was dispensed a 30-day supply of an inhalation drug and \$33 for each subsequent month, or \$66 for a 90-day supply.¹³ As of December 1, 2008, dispensing fees for inhalation drugs were still paid at this same rate.

Medicare Payment and Coding for Albuterol and Levalbuterol

January 1, 2003–December 31, 2004. Medicare payment and coding for albuterol and levalbuterol have undergone several changes since 2003 (see Table 1 on page 6 for details).¹⁴ In 2003 and 2004, albuterol and levalbuterol were both paid for under the same HCPCS code (J7619).¹⁵ At that time, the payment amount for this code was based on the median AWP of all versions of both drugs. In 2003, this resulted in a Medicare payment amount of \$0.47 per milligram (mg) of albuterol or per 0.5 mg of levalbuterol (despite levalbuterol’s much-higher AWP).¹⁶ In 2004, Medicare paid \$0.39 for these dosages of both drugs.

January 1, 2005–June 30, 2007. Effective January 1, 2005, CMS established separate HCPCS codes and separate payment amounts for albuterol (J7613) and levalbuterol (J7614).¹⁷ At the same time, CMS also implemented the ASP methodology as mandated by the MMA. As a result, in the first quarter of 2005, the Medicare payment amount for albuterol decreased to \$0.07 per mg, while the Medicare payment amount for levalbuterol increased to \$1.28 per 0.5 mg. Between January 1, 2005, and June 30, 2007, Medicare payment amounts varied slightly from quarter to quarter. However, Medicare

¹² 69 Fed. Reg. 47488, 47549 (Aug. 5, 2004).

¹³ 42 CFR § 414.1001(c) and (d).

¹⁴ For the purpose of this review, albuterol and levalbuterol refer to unit-dose forms of these drugs; this review does not include the concentrated forms.

¹⁵ 68 Fed. Reg. 50428, 50450 (Aug. 20, 2003).

¹⁶ For treatment purposes, 1 mg of albuterol is generally equivalent to 0.5 mg of levalbuterol.

¹⁷ CMS, “January 2005 Payment Allowance Limits for Medicare Part B Drugs.” Downloaded from a link entitled “Jan 2005 ASP Pricing File and ASP NOC Pricing File.” Available online at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02a_2005aspfiles.asp#TopOfPage. Accessed on March 30, 2009.

continued to pay for albuterol and levalbuterol separately during this time.

July 1, 2007–March 31, 2008. CMS reestablished a single HCPCS code (Q4094) for albuterol and levalbuterol effective July 1, 2007, as described in a May 2007 coding announcement.¹⁸ Thus, as of July 1, 2007, the Medicare payment amount for the code was based on the volume-weighted ASP for both albuterol and levalbuterol. According to the coding announcement, this change was made to ensure that payments reflected the “grandfathering” provision of section 1847A of the Act, which states:

With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.¹⁹

This coding change had a substantial impact on the Medicare payment amounts for both drugs. The Medicare payment amount for albuterol in the third quarter of 2007 was about 6.5 times higher than the payment amount in the second quarter (\$0.08 per mg compared to \$0.53 per mg). However, the payment amount for levalbuterol had decreased by almost two-thirds (from \$1.54 per 0.5 mg to \$0.53 per 0.5 mg).

April 1, 2008–Present. Section 112(b)(2) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Extension Act) established a special rule that addressed the application of the “grandfathering” provision of the Act.²⁰ This provision of the Extension Act provides flexibility in payment determinations designed to yield the lowest payment amount for certain drugs, including albuterol and levalbuterol. More specifically, effective April 1, 2008, this provision allows payment amounts for single-source drugs that are treated as multiple-source drugs under the grandfathering clause to be based on the lower of (1) the payment amount determined when the grandfathering clause

¹⁸ CMS Coding Announcement. Available online at http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf. Accessed on August 25, 2008.

¹⁹ Section 1847A(c)(6)(C)(ii) of the Act. CMS’s change affected Medicare payment for several other drugs as well. We did not examine the potential impact on Medicare expenditures for any drugs other than albuterol and levalbuterol.

²⁰ Section 1847A(c)(6)(C)(ii) of the Act.

is applied or (2) the payment amount when the grandfathering clause is not applied.²¹

Effective April 1, 2008, CMS implemented these provisions of the Extension Act by establishing separate HCPCS codes and payment amounts for albuterol and levalbuterol. By doing so, CMS set the payment amount for albuterol in the second quarter of 2008 at \$0.04 per mg and for levalbuterol at \$0.28 per 0.5 mg. This is a 92-percent decrease in the payment amount for albuterol and a 47-percent decrease for levalbuterol. A summary of the different payment and coding methodologies and their impact on Medicare payment amounts is presented in Table 1.

Table 1: Medicare Payment Amounts for Albuterol and Levalbuterol

| | 95% of AWP | 80% of AWP | 106% of ASP | | | | |
|----------------------------------|------------|------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 2003 | 2004 | 2005 (1 st Qtr) | 2006 (1 st Qtr) | 2007 (2 nd Qtr) | 2007 (3 rd Qtr) | 2008 (2 nd Qtr) |
| Combined Payment Codes | | | | | | | |
| Albuterol (unit dose), 1 mg | \$0.47 | \$0.39 | - | - | - | \$0.53 | - |
| Levalbuterol (unit dose), 0.5 mg | | | | | | | |
| Separate Payment Codes | | | | | | | |
| Albuterol (unit dose), 1 mg | | - | \$0.07 | \$0.06 | \$0.08 | - | \$0.04 |
| Levalbuterol (unit dose), 0.5 mg | | - | \$1.28 | \$1.34 | \$1.54 | - | \$0.28 |

Source: Quarterly Medicare payment amounts from CMS's Web site.

Medicare Spending for Albuterol and Levalbuterol

In 2004, albuterol and levalbuterol accounted for 31 percent (\$404 million) of the \$1.3 billion Medicare spent on inhalation drugs. Following the MMA-mandated change to an ASP-based reimbursement methodology, spending on albuterol and levalbuterol dropped to \$234 million in 2005 (30 percent of the \$784 million spent on all inhalation drugs). By 2007, total Medicare spending for albuterol and levalbuterol had increased to \$385 million, an amount approaching the pre-ASP level. These drugs accounted for nearly 40 percent of the \$1 billion Medicare spent on inhalation drugs.²² See Table 2 for details

²¹ Section 1847A(b)(7)(A) of the Act.

²² Medicare Part B Extract and Summary System (BESS) (98 percent of claims reported). Accessed on June 17, 2008.

on total Medicare payments for albuterol and levalbuterol from 2003 through 2007.

Table 2: Total Medicare Spending on Albuterol and Levalbuterol

| | 95% of AWP | 80% of AWP | 106% of ASP | | |
|---|----------------------|----------------------|----------------------|----------------------|----------------------|
| | 2003 | 2004 | 2005 | 2006 | 2007* |
| Combined Payment Codes | | | | | |
| Albuterol (unit dose), 1 mg; levalbuterol (unit dose), 0.5 mg | \$484 million | \$404 million | - | - | \$162 million |
| Separate Payment Codes | | | | | |
| Albuterol (unit dose), 1 mg | - | - | \$57 million | \$39 million | \$17 million |
| Levalbuterol (unit dose), 0.5 mg | - | - | \$177 million | \$334 million | \$206 million |
| Total Medicare spending on albuterol and levalbuterol | \$484 million | \$404 million | \$234 million | \$373 million | \$385 million |

*Albuterol and levalbuterol had separate payment amounts in the first half of 2007 and combined payment amounts for the second half. Source: BESS 2003–2006 data accessed on June 11, 2007; BESS 2007 data accessed on July 15, 2008.

METHODOLOGY

Sample Selection

Our sample was limited to beneficiaries who had received albuterol or levalbuterol continuously from the first half of 2003 through the fourth quarter of 2007, provided by the same supplier and prescribed by the same physician. It was also limited to suppliers and physicians that were not under current investigation. Therefore, our sample may be projected only to beneficiaries who meet these criteria.

We obtained 100 percent of Medicare DME claims for albuterol and levalbuterol from CMS’s National Claims History file for 2003 through 2007. Using these data, we first identified the beneficiaries with claims for albuterol/levalbuterol (HCPCS code Q4094) in the fourth quarter of 2007 (319,849 beneficiaries). Among this group, we identified all of the beneficiaries who had at least one albuterol or levalbuterol claim in both the first and second halves of each year from 2003 through 2007 (36,585 beneficiaries).

We further limited our sample to include only the beneficiaries who, according to the claims data, had not changed their prescribing physicians and suppliers during this time. Using the group of beneficiaries with albuterol and levalbuterol claims in each half of 2003 through 2007, we matched the physician’s unique physician

identification number (UPIN) listed on every claim in the first half of 2007 to the UPIN listed on every albuterol and levalbuterol claim since January 2003. We then matched the supplier's provider identification number to each provider identification number listed on each claim during this time. We selected only those beneficiaries whose claims always listed the same UPIN and provider identification number between 2003 and 2007. In total, 7,426 beneficiaries met these criteria (2 percent of the 319,849 beneficiaries with albuterol/levalbuterol claims in the fourth quarter of 2007).

We randomly selected a sample of 400 beneficiaries from the group of 7,426 beneficiaries. We removed from our sample beneficiaries who received drugs from the six suppliers that were under investigation.²³ Our final sample of 312 beneficiaries were prescribed inhalation drugs by 304 physicians and provided inhalation drugs by 154 suppliers.

Data Collection

Because the HCPCS codes used prior to 2005 and in the second half of 2007 did not enable us to differentiate between albuterol and levalbuterol from the claims data alone, we contacted the supplier and physician for each beneficiary. We used the provider and physician identification numbers listed on the claim and cross-referenced these to address databases (i.e., National Supplier Clearinghouse and UPIN Registry) to contact each beneficiary's supplier and prescribing physician.

Supplier requests. For each beneficiary, we requested that the supplier complete a dispensing table to show the drug dispensed, the dates dispensed, the drug's strength and volume, and the number of vials provided. We also requested copies of the beneficiary's original physician-signed prescriptions for albuterol and/or levalbuterol. If a beneficiary changed between the two drugs from January 1, 2005, through December 31, 2007, we asked the supplier to describe what prompted each change.

At the end of June 2008, we sent requests to the 154 suppliers associated with the 312 beneficiaries. As of September 2008, we had

²³ These six suppliers provided inhalation drugs to 88 of the 400 beneficiaries.

received responses from 143 suppliers for 300 beneficiaries.²⁴ ²⁵ Two beneficiaries were not included in any of the analyses because the supplier reported that they were on compounded versions of the drugs the entire time, yielding a total possible sample size of 298 (response rate of 96 percent).²⁶

Physician requests. For each beneficiary in our sample, we asked his or her physician to provide the beneficiary's albuterol and levalbuterol prescription history from January 1, 2003, through December 31, 2007. By doing so, we were able to determine whether and how often the beneficiary changed between albuterol and levalbuterol. We asked each physician to report the reason for (1) changes from albuterol to levalbuterol on or after January 1, 2005; and (2) changes from levalbuterol to albuterol on or after July 1, 2007. For these changes, we projected the percentages to our population.

We sent requests to the 304 physicians who prescribed albuterol or levalbuterol to the 312 beneficiaries at the end of June 2008. As of September 2008, we had received responses from 181 physicians for 186 beneficiaries that could be included in the analysis of physician responses (response rate of 60 percent). In addition, we received physician responses for 46 beneficiaries who could not be included in the analysis because (1) the physician reported prescribing both drugs to the beneficiary at the same time, (2) the physician stated that neither of the drugs was prescribed for the beneficiary during the requested timeframe, (3) the physician reported that he or she had never seen the beneficiary (at least not in the last 5 years), or (4) the physician did not have records identifying the drug and/or dates prescribed.²⁷

²⁴ Six suppliers returned their beneficiary surveys after the deadline and after the analyses were completed. Therefore, these were not included in the analyses. One supplier for one beneficiary reported that it never provided either drug to the beneficiary. There were an additional four suppliers (accounting for five beneficiaries) that we referred for investigation because their surveys were returned to us marked undeliverable.

²⁵ We sent up to two follow-up surveys and made several attempts to contact nonresponding suppliers.

²⁶ Pharmacy compounding is a practice in which pharmacists combine, mix, or alter ingredients, such as albuterol and ipratropium bromide, to create unique medications that meet specific needs of individual patients.

²⁷ For cases in which physicians responded that they prescribed neither drug or did not treat the beneficiaries, we will provide our Office of Investigations (OI) with information about the supplier that billed for the drug.

Among the nonresponding physicians, 72 physicians associated with 73 beneficiaries (23 percent) did not return completed surveys and had no contact with our office.²⁸ An additional four physicians declined to respond to our request, two addresses could not be found, and one doctor had died and the office closed over a year ago.

Data Analysis

Because the suppliers dispensed the drugs to the beneficiaries, we used their responses to determine the percentage of beneficiaries with drug utilization changes. We calculated the percentage of beneficiaries who were (1) on albuterol in 2004 and then changed to levalbuterol between January 1, 2005, and July 1, 2007 (following the change to ASP); and (2) on levalbuterol as of June 2007 (before the payment coding change) and then changed to albuterol in the second half of 2007.²⁹ ³⁰ We also calculated the percentage of beneficiaries who were changed to the less profitable drug during each of these periods.

Once we determined the number of beneficiaries who were changed from one drug to the other, we compared the prescription reports from those beneficiaries' suppliers with those of the corresponding physicians. Using the physician responses, we determined what prompted the physicians to change the beneficiaries from albuterol to levalbuterol between January 1, 2005, and June 30, 2007, or from levalbuterol to albuterol in the second half of 2007. Because of a low physician response rate and a small sample size, we did not make projections based on physician responses.

Additionally, for the beneficiaries who were changed to a more profitable drug (i.e., changed to levalbuterol between January 1, 2005, and June 30, 2007; or changed to albuterol after June 30, 2007), we compared physician and supplier responses. We received both physician and supplier responses for 50 of the

²⁸ We sent up to two follow-up surveys to physicians who had not responded to the original request by the due date.

²⁹ We analyzed only changes between albuterol and levalbuterol; supplier and physician responses indicating changes between compounded drugs (e.g., albuterol/ipratropium bromide) were excluded from each analysis.

³⁰ We projected the results to the population for the first change (i.e., from albuterol to levalbuterol following the change to ASP). However, because we selected a subset of beneficiaries for the second change (i.e., beneficiaries on levalbuterol as of June 2007 who were changed to albuterol in the second half of 2007), our sample size for this analysis was reduced to 63 beneficiaries. Therefore, we were unable to reliably project this percentage.

78 beneficiaries with this type of change. We calculated the number of beneficiaries whose suppliers reported changes that the physicians did not report.³¹

To estimate the impact of changing between the two drugs on supplier reimbursement, we compared Medicare's quarterly payments for albuterol and levalbuterol to the estimated supplier acquisition costs. We based our estimate of acquisition costs in each quarter on the manufacturer-reported ASPs reflecting sales during that same quarter. We multiplied the difference between supplier acquisition cost and average reimbursement by 90 vials to approximate the net difference per month.^{32 33} Using claims data in CMS's National Claims History file and information from supplier responses, we also determined the average spending per beneficiary in our sample on albuterol and levalbuterol in the first half of each year from 2003 to 2007.³⁴

Limitations

We limited our sample to include beneficiaries with albuterol or levalbuterol claims during the first and second half of each year between January 1, 2003, and December 31, 2007, who had the same physician and the same supplier for all 5 years. Because beneficiaries may change their doctors or suppliers within a 5-year period, our sample may not be representative of all beneficiaries who were prescribed inhalation drugs.

By selecting a sample of beneficiaries who each had only one supplier and one physician, we may also have eliminated potentially fraudulent DME suppliers. As demonstrated in a prior OIG report, beneficiaries in

³¹ As previously noted, this analysis includes physician responses. We did not project these figures because of a low sample size and a low physician response rate.

³² Prescribing information on the Food and Drug Administration's Web site states that patients may benefit from using 2.5 mg of albuterol or 1.25 mg of levalbuterol three times a day, which would be approximately 90 vials per month.

³³ We used the most common dosages per vial reported by suppliers for each drug: 2.5 mg/3 milliliter (mL) of albuterol and 1.25 mg/3 mL of levalbuterol. Levalbuterol is available in three doses: 0.31 mg, 0.63 mg, and 1.25 mg. The manufacturer prices each vial the same, regardless of the dose it contains. However, CMS bases the reimbursement on the dose in each vial (i.e., per mg). This creates a potential disconnection between pricing and reimbursement and may produce an incentive for manufacturers to purchase the highest dosage of 1.25 mg/3 mL.

³⁴ Because we could not differentiate between albuterol and levalbuterol claims in 2003 and 2004, to calculate the average albuterol and levalbuterol spending, we used the information from the supplier responses to identify the drug listed on the claim.

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South Florida, a high-risk area for fraudulent and excessive DME billings, have a much higher rate of multiple suppliers per beneficiary than anywhere else. Because we removed the beneficiaries with multiple suppliers, our percentage of beneficiaries who were changed to a more profitable drug and average spending calculations may be lower than if the beneficiaries associated with these suppliers were included.

Our analysis of supplier reimbursement includes only Medicare payments for the ingredient cost portion. We did not analyze the impact of dispensing fees (which were the same for both drugs) in our review. In addition, we did not address clinical issues associated with either drug.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” approved by the Council of the Inspectors General on Integrity and Efficiency.

Shifts in utilization patterns for albuterol and levalbuterol coincided with changes in payment and coding

Medicare payment and coding for albuterol and levalbuterol have undergone several changes since 2003. Between 2003 and 2007,

utilization patterns for both drugs among beneficiaries fluctuated noticeably—almost always shifting toward the drug with the more profitable cost and reimbursement difference (i.e., more favorable for the supplier from a reimbursement perspective). Figure 1 on page 16 illustrates the changes in utilization among beneficiaries from 2003 to 2007.

In 2003 and 2004, Medicare reimbursement favored albuterol and nearly all beneficiaries received that drug

Albuterol and levalbuterol were both included in the same HCPCS code and paid by Medicare at the same AWP-based rate in 2003 and 2004. However, the actual acquisition cost of albuterol was much lower than the actual acquisition cost of levalbuterol.³⁵ We estimate that in the fourth quarter of 2004, suppliers could purchase a typical monthly supply (90 vials) of albuterol for around \$19, while a similar supply of levalbuterol cost \$164. Medicare reimbursed suppliers approximately \$88 for either drug in the fourth quarter of 2004, meaning that suppliers were reimbursed almost five times their cost for albuterol, but substantially less than their cost for levalbuterol (almost 50 percent below their average acquisition cost for a month's supply).

Ninety-seven percent of beneficiaries received albuterol in the fourth quarter of 2004, but only 3 percent received levalbuterol (based on supplier responses). These figures were relatively constant during the entire period from January 1, 2003, through December 31, 2004. Refer to Appendix A for the percentages and confidence intervals cited in this report.

Between January 2005 and June 2007, Medicare reimbursement favored levalbuterol; during that period, one-quarter of beneficiaries who were using albuterol were changed to levalbuterol

Effective January 1, 2005, CMS established separate HCPCS codes and separate payment amounts for albuterol and levalbuterol. At the same time, CMS implemented the ASP methodology as mandated by

³⁵ Average acquisition cost was based on manufacturer-reported ASP data from the quarter under review.

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the MMA. As a result, instead of favoring albuterol, reimbursement became much more favorable for levalbuterol.

During the initial quarter after the 2005 coding and reimbursement change, Medicare’s payment for the typical monthly supply of albuterol fell from \$88 to \$15, while payment for levalbuterol jumped from \$88 to \$288. According to ASP data, suppliers paid, on average, \$14 for a monthly supply of albuterol and \$171 for levalbuterol. In other words, suppliers were now being reimbursed roughly at cost for albuterol, but 68 percent above cost for levalbuterol. Medicare reimbursement continued to greatly favor levalbuterol between January 2005 and July 2007, even though actual differences between Medicare payment and acquisition costs for the two drugs shifted slightly (see Table 3).

Table 3: Average Reimbursement and Cost Difference for a Monthly Supply of Albuterol and Levalbuterol (Fourth Quarter 2004 and Second Quarter 2007)

| Timeframe | Supplier Acquisition Cost for Albuterol | Medicare Reimbursement for Albuterol | Albuterol Difference | Supplier Acquisition Cost for Levalbuterol | Medicare Reimbursement for Levalbuterol | Levalbuterol Difference |
|-----------|---|--------------------------------------|----------------------|--|---|-------------------------|
| 4Q 2004 | \$19.10 | \$87.75 | \$68.65 | \$164.25 | \$87.75 | -\$76.50 |
| 1Q 2005 | \$14.01 | \$14.63 | \$0.62 | \$171.00 | \$287.55 | \$116.55 |
| 1Q 2006 | \$17.41 | \$13.50 | -\$3.91 | \$207.00 | \$301.05 | \$94.05 |
| 2Q 2007 | \$11.25 | \$18.23 | \$6.98 | \$211.05 | \$345.38 | \$134.33 |

Note: All figures are average monthly amounts in each quarter for 225 mg of albuterol and 112.5 mg of levalbuterol. Refer to Appendix B for the difference between reimbursement and cost for all quarters between October 1, 2004, and December 31, 2007. Source: Medicare payment amounts from CMS’s Web site; OIG analysis of supplier acquisition data.

Coinciding with the payment and coding changes, a number of beneficiaries began receiving levalbuterol in place of albuterol. Twenty-five percent of beneficiaries who were on albuterol in 2004 were changed to levalbuterol between January 1, 2005, and June 30, 2007. In our sample, almost one-third of these changes occurred in the initial two quarters after the payment and coding changes.

Prescription changes in the opposite direction, from levalbuterol to albuterol, rarely happened during this period. Three percent of beneficiaries were changed from levalbuterol to albuterol between January 1, 2005, and June 30, 2007. In our sample of beneficiaries, more than half (five of nine) of these changes occurred in May or June of

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2007, i.e., after the payment and coding changes were announced but before they took effect.

From July through December 2007, Medicare reimbursement again favored albuterol; two-thirds of the beneficiaries in our sample who had been using levalbuterol were changed to albuterol

As of July 1, 2007, CMS recombined albuterol and levalbuterol into a single HCPCS code and calculated the payment amount based on the volume-weighted ASP for both drugs. As a result, Medicare reimbursement again began to favor albuterol.

Under the new payment and coding method, the Medicare payment amount for a typical monthly supply of albuterol increased from \$18 in the second quarter of 2007 to \$118 in the third quarter. The payment amount for levalbuterol decreased from \$345 to \$118. We estimate that suppliers' acquisition cost for a monthly supply of albuterol averaged just \$12, compared to \$230 for levalbuterol (see Table 4). In other words, suppliers were reimbursed almost 10 times their cost for albuterol, but roughly half their cost for levalbuterol. In fact, for albuterol, the difference between Medicare reimbursement and acquisition cost was greater in the third quarter of 2007 than in the fourth quarter of 2004 (\$106 compared to \$69), i.e., before the MMA-mandated change to ASP took effect.

Table 4: Average Reimbursement and Cost Difference for a Monthly Supply of Albuterol and Levalbuterol (Second to Fourth Quarter 2007)

| Timeframe | Supplier Acquisition Cost for Albuterol | Medicare Reimbursement for Albuterol | Albuterol Difference | Supplier Acquisition Cost for Levalbuterol | Medicare Reimbursement for Levalbuterol | Levalbuterol Difference |
|-----------|---|--------------------------------------|----------------------|--|---|-------------------------|
| 2Q 2007 | \$11.25 | \$18.23 | \$6.98 | \$211.05 | \$345.38 | \$134.33 |
| 3Q 2007 | \$12.38 | \$118.13 | \$105.75 | \$229.50 | \$118.13 | -\$111.37 |
| 4Q 2007 | \$9.45 | \$94.28 | \$84.83 | \$234.00 | \$94.28 | -\$139.72 |

Note: All figures are average monthly amounts in each quarter for 225 mg of albuterol and 112.5 mg of levalbuterol. Refer to Appendix B for the differences in reimbursement and cost for all quarters between October 1, 2004, and December 31, 2007. Source: Medicare payment amounts from CMS's Web site; OIG analysis of supplier acquisition data.

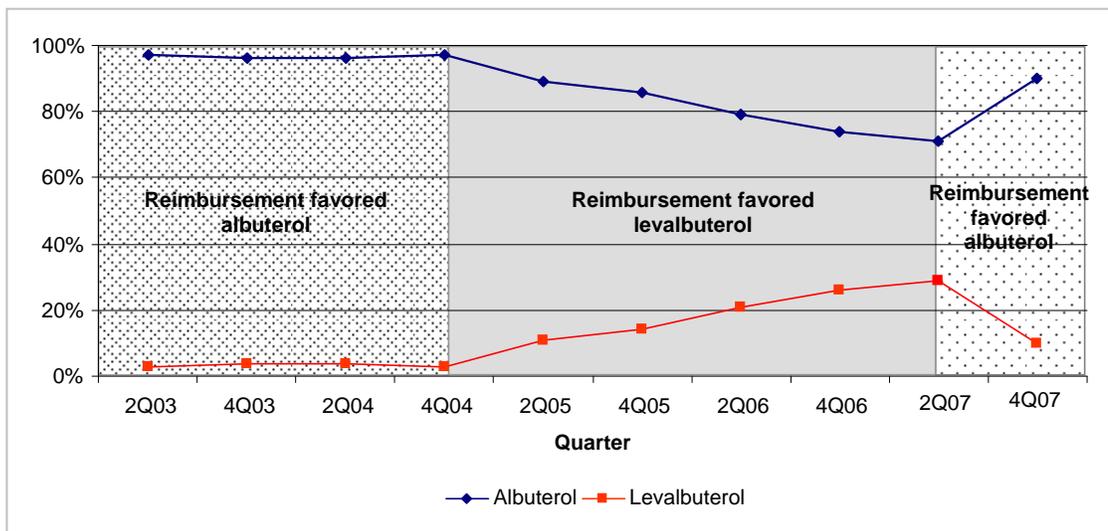
Suppliers reported that two-thirds of beneficiaries in our sample who received levalbuterol as of June 2007 were changed to albuterol after the July 2007 payment and coding change.³⁶ Almost all (95 percent) of

³⁶ Because only the 63 beneficiaries who were on levalbuterol as of June 2007 were included in this analysis, we are unable to reliably project this figure.

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these changes occurred in the initial quarter after the change became effective, with more than half (54 percent) occurring in July. As previously mentioned, an additional five beneficiaries in our sample who were receiving levalbuterol moved to albuterol in May or June 2007—after the payment and coding changes were announced but before they took effect. By December 31, 2007, 90 percent of beneficiaries were receiving albuterol and 10 percent were receiving levalbuterol.

Figure 1: Percentage of Beneficiaries on Albuterol and Levalbuterol (2003–2007)



Source: OIG analysis of supplier surveys, 2008.

The April 1, 2008, payment and coding change led to a substantial decrease in Medicare payments for both drugs compared to the first quarter of 2008; as a result, albuterol was reimbursed at close to cost and levalbuterol reimbursement remained substantially below cost

As of April 1, 2008, CMS had implemented provisions of the Extension Act by reestablishing separate HCPCS codes and payment amounts for albuterol and levalbuterol. As a result, Medicare’s payment amount for albuterol became much more reflective of the acquisition cost. We estimate that in the second quarter of 2008, a month’s supply of albuterol cost \$9 and Medicare reimbursed \$10. However, for levalbuterol, the average acquisition cost for a month’s supply was \$205, but Medicare reimbursement was \$63 (69 percent below cost).

This change significantly decreased total Medicare payments for albuterol and levalbuterol. In the first quarter of 2008, when the

payment code and amount were still combined, Medicare paid \$75 million for both drugs.³⁷ However, because of the decrease in each drug’s payment amount on April 1, 2008, Medicare paid an average of only \$7 million per quarter for these two drugs in the last three quarters of 2008. In total, Medicare paid \$20 million for both drugs during this time (\$9 million for albuterol and \$11 for levalbuterol).³⁸

Despite the move to ASP, average per-beneficiary spending on albuterol and levalbuterol actually increased above pre-MMA levels

In the first half of 2003 (when payment was based on AWP), Medicare spent an average of \$506 on

albuterol and levalbuterol for each beneficiary. Because almost all beneficiaries (97 percent) were receiving albuterol rather than levalbuterol, the former accounted for the vast majority of this spending. The change to an ASP-based reimbursement system in January 2005 lowered the Medicare payment amount for albuterol by 83 percent. However, because utilization began slowly shifting to levalbuterol, per-beneficiary spending did not decline proportionally.

As the number of beneficiaries shifting to levalbuterol increased, so did the average spending per beneficiary. Between January 1 and June 30, 2007, when more than a quarter of beneficiaries were receiving levalbuterol, the average per-beneficiary spending was actually higher than pre-MMA levels. During these 6 months, Medicare paid an average of \$600 per beneficiary for both albuterol and levalbuterol, or \$94 more per beneficiary than in the first half of 2003. Figure 2, on page 18, shows how average per-beneficiary spending for the two drugs changed between 2003 and the first half of 2007, including how levalbuterol began to account for a much larger share of total payments.

Although the majority of beneficiaries remained on albuterol, the quarter who had been changed to levalbuterol contributed to a total increase in spending on both drugs. The 29 percent of all beneficiaries on levalbuterol by June 2007 represented 90 percent of total spending

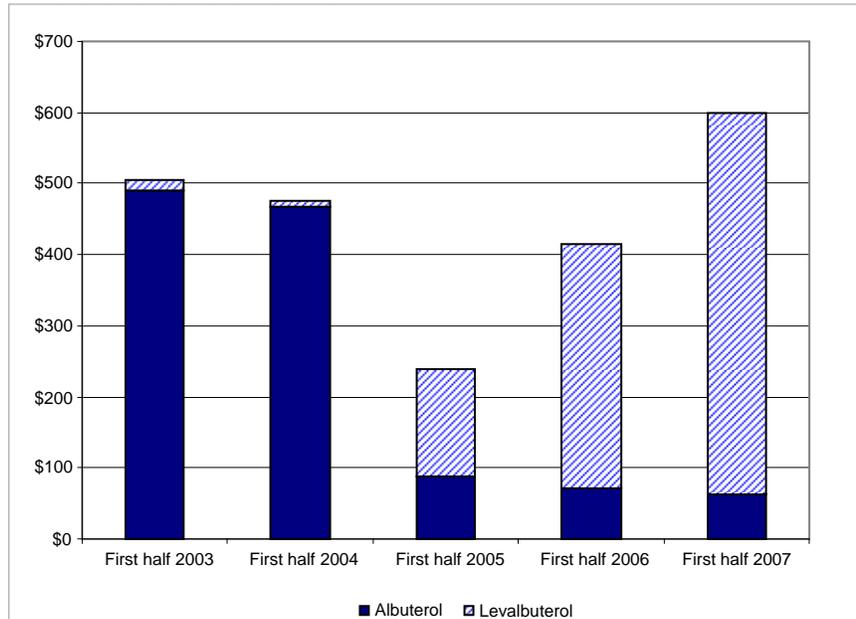
³⁷ Because the payment codes and payment amounts for albuterol and levalbuterol were combined in the first quarter of 2008, we cannot determine payments for either drug.

³⁸ Medicare BESS data (90 percent of claims reported). Accessed on February 20, 2009.

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for both drugs in the first half of 2007. Medicare paid an average of \$88 per beneficiary for those who were on albuterol in the first half of 2007, but \$1,776 per beneficiary on levalbuterol.

Figure 2: Average Amount Medicare Paid per Beneficiary for Albuterol and Levalbuterol



Note: Because levalbuterol and albuterol had combined HCPCS codes in the second half of 2007, we analyzed spending for the first half of 2007 and the first half of the prior years to remain consistent.
Source: OIG analysis of National Claims History file, 2008.

Physicians in our sample typically cited clinical reasons for changing beneficiaries from albuterol to levalbuterol, but financial reasons for changing in the opposite direction

Physicians who responded to our data request indicated that changes in beneficiary prescriptions for albuterol and levalbuterol occurred for both

clinical and financial reasons.³⁹

Changes occurring between January 1, 2005, and June 30, 2007. We received physician responses for 36 of the 69 beneficiaries in our sample who were changed from albuterol to levalbuterol between January 1, 2005, and June 30, 2007 (i.e., when levalbuterol became the more favorable drug from a reimbursement perspective). For 23 of the 36 beneficiaries (64 percent), physicians reported that the changes occurred because of clinical reasons (e.g., albuterol has side effects,

³⁹ Given the small sample size and low response rate from physicians, we cannot accurately project these results with confidence.

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levalbuterol is a more efficacious drug). These physicians had previously prescribed albuterol to these beneficiaries for an average of 2.7 years prior to the change.⁴⁰

Physicians for just three beneficiaries in our sample (8 percent) cited financial reasons for the change to levalbuterol during this same period. For example, one physician reported changing a beneficiary after the supplier mentioned the Medicare payment guidelines for the two drugs. For an additional three beneficiaries (8 percent), physicians reported that the changes occurred because the supplier actually requested levalbuterol to be prescribed in place of albuterol. In the remaining cases, reasons given for the changes include (1) other physicians changed the beneficiaries' prescriptions,⁴¹ and (2) the beneficiaries requested levalbuterol. In some cases, the physicians' offices had no documentation of the reasons for the changes.

Changes occurring between July 1 and December 31, 2007. We received physician responses for only 12 of the 41 beneficiaries in our sample who were changed from levalbuterol to albuterol between July 1 and December 31, 2007. For 7 of 12 the beneficiaries (58 percent), physicians reported that the prescriptions were changed because of financial concerns. For example, one physician reported that he changed a beneficiary's prescription because that patient's "insurance didn't cover levalbuterol." Physicians also reported that changes to Medicare reimbursement prompted the prescription changes. Physician responses for four of these seven beneficiaries indicated that they were originally changed from albuterol to levalbuterol because of albuterol's side effects.

During this same time, only one beneficiary was changed from levalbuterol to albuterol because of clinical reasons and an additional two because the beneficiaries requested albuterol.

⁴⁰ The average length of time on albuterol may be longer, but we did not request prescription history information prior to January 1, 2003.

⁴¹ In these cases, the physician reported that the beneficiary was changed while being treated at a hospital by a different doctor. These claims would be covered under Medicare Part A and would not appear in the claim files we used to select the beneficiaries in our sample.

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In a small number of cases, physicians were unaware that beneficiaries had been changed to a different drug

Among the 50 beneficiaries with supplier-reported albuterol or levalbuterol changes for whom we also received physician responses, the suppliers' dispensing history did not always match what the physicians reported prescribing. In particular, physicians for 19 beneficiaries in our sample reported no knowledge of or consent to such changes.⁴²

In most of these cases (12 of 19 beneficiaries), the physician never reported any prescription changes from 2003 through 2007 while the supplier reported two changes between albuterol and levalbuterol that coincided with the Medicare payment and coding changes. For example, one physician reported that only albuterol was prescribed for a particular beneficiary from January 1, 2003, until December 31, 2007. The supplier, however, reported that the beneficiary was changed from albuterol to levalbuterol in March 2006 and then changed back to albuterol in September 2007 (after the HCPCS coding change).

The remaining seven beneficiaries had one supplier-reported change that did not match their physicians' prescription histories (all but one of these from levalbuterol to albuterol following the coding change on July 1, 2007).

⁴² If requested, we will provide information about these suppliers to CMS and OI.

► C O N C L U S I O N

Albuterol and levalbuterol are used to treat the same symptoms. Although some clinical studies suggest that levalbuterol has greater efficacy than albuterol, other trials have failed to detect any advantage to the patient. It is beyond the scope of our study to address such clinical issues. However, our findings illustrate that payment and coding issues, and not just clinical concerns, may affect which of the two drugs is prescribed and provided to Medicare beneficiaries.

Prior to 2005, almost all of the beneficiaries in our review were receiving albuterol rather than levalbuterol. Between January 2005 and June 2007, when Medicare reimbursement shifted to favor the more expensive levalbuterol, one-quarter of beneficiaries were changed from albuterol to the costlier product. Although a number of physicians cited clinical reasons for changing prescriptions, reimbursement considerations may have also played a role—especially given that some changes appear to have been completed by suppliers without the physicians' knowledge and that the majority of beneficiaries (75 percent) remained on albuterol.

Effective July 1, 2007, payment rates were again significantly changed when CMS recombined the HCPCS codes for albuterol and levalbuterol and began calculating the Medicare payment amount as a volume-weighted average of both drugs. Because most suppliers could not acquire levalbuterol at a price below the reimbursement amount, many may have lost money by providing the drug. At that time, many beneficiaries were changed back to albuterol, even though in some cases (according to physicians), albuterol had initially caused side effects. At this same time, however, the payment situation not only created a disincentive for levalbuterol, but also caused albuterol to be reimbursed at more than 10 times its cost. Such a wide gulf between cost and reimbursement was exactly what the ASP-based methodology was created to avoid. For example, such large financial incentives for supplying albuterol may have influenced a small number of suppliers in our sample to change beneficiaries to a new drug without the physicians' consent.

As of April 1, 2008, CMS implemented a provision of the Extension Act that once again lowered albuterol reimbursement so that payment more accurately reflected acquisition cost. However, the same provision prevented CMS from addressing any underpayment for levalbuterol.

C O N C L U S I O N

Although our findings were limited to a small and specific subset of beneficiaries, there may have been similar utilization shifts between albuterol and levalbuterol among Medicare beneficiaries outside our sample. Because the Medicare payment amounts and acquisition costs presented in this report were based on national cost and reimbursement data, all suppliers—not just the ones included in our sample—would likely have been subject to the same incentives to dispense one drug instead of the other. Medicare’s total spending for the two drugs reflects this fact, as the program paid almost as much for albuterol and levalbuterol combined in 2007 as it did in 2004, despite the substantial changes to the payment amount under the ASP methodology. Given that the number of Medicare beneficiaries with inhalation drug claims did not increase between 2004 and 2007, this could have occurred only if a large number of beneficiaries, and not just the limited subset on which our analysis was based, were shifted to the drug with the most favorable reimbursement.

In some cases, this could not only have a significant impact on total Medicare spending but also limit beneficiary access to a potentially more effective product. When Congress and CMS make reimbursement and coding decisions, it is important they take into consideration that these new policies may affect what drug a beneficiary is prescribed. In some cases, this may limit access to a potentially more effective product; in others, utilization could be driven toward a more expensive product that offers no clinical advantage. In future studies, OIG will continue to monitor the utilization of and payment for these and other drugs, with the goal of identifying inappropriate Medicare payments.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS stated that the agency is aware of the impact that changes in payment methodologies can have on access to prescription drugs. However, CMS noted that in the case of albuterol and levalbuterol, changes to coding and pricing were not discretionary but instead were made to comply with legislative mandates. CMS stated that the agency has monitored and will continue to monitor spending and utilization for both drugs to help ensure price stability and access while fulfilling legal mandates.

In addition, CMS provided several technical comments to our draft report. These technical comments included two items that CMS

C O N C L U S I O N

believes OIG should investigate further. These items are: (1) cases in which physicians were reportedly unaware of the medication changes; and (2) the clinical rationales for changing medications, including whether reports of clinical complications truly reflect actual complications.

OIG will review cases in which prescription changes occurred without the physicians' knowledge to determine whether further investigation is warranted. However, in regard to the second item, the clinical rationales we obtained from physicians provide sufficient justifications for changes to albuterol and levalbuterol prescriptions, and therefore no further investigation is necessary. In addition, as CMS pointed out, while it is important to know the rationales for medication changes, the agency (as well as OIG) is limited in its ability to mandate and regulate a physician's decision to prescribe or not to prescribe a drug.

We did not make any changes to the report based on CMS's comments. For the full text of CMS's comments, see Appendix C.

Table A-1: Confidence Intervals for Percentages

| Statistic | Sample Size | Percentage | 95% Confidence Interval |
|---|-------------|------------|-------------------------|
| Percentage of beneficiaries who were on albuterol in the fourth quarter of 2004 (according to suppliers) | 281 | 96.8% | 94.0% to 98.5%* |
| Percentage of beneficiaries who were on levalbuterol in the fourth quarter of 2004 (according to suppliers) | 281 | 3.2% | 1.5% to 6.0%* |
| Percentage of beneficiaries on albuterol in 2004 who were changed to levalbuterol between January 1, 2005, and June 30, 2007 (according to suppliers) | 272 | 25.0% | 19.8% to 30.2% |
| Percentage of beneficiaries on levalbuterol who were changed to albuterol between January 1, 2005, and June 30, 2007 (according to suppliers) | 281 | 3.2% | 1.5% to 6.0%* |
| Percentage of beneficiaries on albuterol by December 31, 2007 (according to suppliers) | 280** | 89.6% | 85.5% to 93.0%* |
| Percentage of beneficiaries on levalbuterol by December 31, 2007 (according to suppliers) | 280** | 10.4% | 7.1% to 14.5%* |
| Percentage of beneficiaries on levalbuterol by June 30, 2007 (according to suppliers) | 279** | 29.4% | 24.0% to 34.8% |

* This confidence interval was calculated with an exact method based on binomial distribution.

** The sample size is not 281 because the beneficiary's supplier reported that it was missing dispensing records.

Source: Office of Inspector General analysis of supplier surveys, 2008.

Table B-1: Average Monthly Difference Between Reimbursement and Cost for Albuterol and Levalbuterol

| Quarter and Year | Monthly Difference for Albuterol | Monthly Difference for Levalbuterol |
|---------------------|----------------------------------|-------------------------------------|
| Fourth quarter 2004 | \$68.65 | -\$76.50 |
| First quarter 2005 | \$0.62 | \$116.55 |
| Second quarter 2005 | \$6.67 | \$136.58 |
| Third quarter 2005 | \$2.11 | \$112.28 |
| Fourth quarter 2005 | -\$1.10 | \$107.33 |
| First quarter 2006 | -\$3.91 | \$94.05 |
| Second quarter 2006 | \$3.90 | \$105.53 |
| Third quarter 2006 | \$4.65 | \$129.15 |
| Fourth quarter 2006 | -\$3.92 | \$95.18 |
| First quarter 2007 | \$0.23 | \$102.38 |
| Second quarter 2007 | \$6.98 | \$134.33 |
| Third quarter 2007 | \$105.75 | -\$111.37 |
| Fourth quarter 2007 | \$84.83 | -\$139.72 |

Source: Medicare payment amounts from the Centers for Medicare & Medicaid Services' Web site; Office of Inspector General analysis of supplier acquisition data.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: JUL 02 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera /S/
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: "Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B" (OEI-03-07-00440)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, "Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B." We appreciate the OIG's continuing efforts to examine payments made under the average sales price methodology. The OIG report presents findings from an analysis of coding and payment changes made to these two inhalation drugs.

The OIG reviewed two specific Medicare Part B drugs, albuterol and levalbuterol, both bronchodilators used to treat asthma and chronic obstructive pulmonary diseases (COPD). Studies have shown a significant incidence of COPD in the adult population.

The OIG concluded that a correlation exists between coding and pricing changes and shifts in prescribing patterns and utilization between the two drugs. Specifically, the OIG found that at times, prescribing patterns and utilization of these drugs shifted toward the more financially profitable drug. The OIG also found that some beneficiaries were switched between the drugs more than once, often correlating with Medicare coding and payment limit changes.

These drugs have been affected by a number of coding and pricing changes since 2003. It is important to recognize that these changes were not discretionary; instead the changes were made in order to comply with legislative mandates. As the OIG noted, in 2003 and 2007, Congress amended the Social Security Act to change the methodology used to pay claims for certain Medicare Part B drugs and specifically certain drugs administered through durable medical equipment. The Centers for Medicare & Medicaid Services (CMS) is aware of the impact that changes in payment methodologies can have on access to prescription drugs. We have and will continue to closely monitor spending and utilization on these drugs to help balance our need to assure stability in prices and access to drugs while discharging our legal mandates.

Page 2 – Daniel R. Levinson

We would like to provide the following technical comments:

- 1) The OIG discussed the additional dispensing fees that are paid to suppliers when dispensing inhalation drugs. These fees can amount to an extra one time fee of \$57 paid to a supplier and an additional \$22-\$33 paid each month thereafter. The existence of these dispensing fees may provide an additional incentive for suppliers to fill more prescriptions for beneficiaries.
- 2) The OIG noted that spending on albuterol and levalbuterol in 2007 approached \$385 million or nearly 40 percent of spending on inhalation drugs. It is important to keep in mind that this represents less than 4 percent of total spending on all Medicare Part B covered drugs.
- 3) The OIG's work investigated the reasons physicians changed drugs prescribed to their beneficiaries. While it is important to know the rationale behind treatment changes, the Agency is limited in its ability to mandate or otherwise regulate the practice of medicine, including a physician's decision to prescribe or to not prescribe a drug.
- 4) The OIG found that physicians cited clinical reasons for changing beneficiaries from albuterol to levalbuterol, but financial reasons for changing back. CMS does not fully understand the interplay between these two rationales. This is further complicated by the OIG's finding that the physicians who switched beneficiaries from albuterol to levalbuterol had previously prescribed albuterol to these beneficiaries for an average of more than 2 years prior to the change which suggests that the beneficiaries had been stabilized on albuterol. A body of clinical evidence appears to show limited clinical complications associated with the use of either of these drugs, and that the emergence of such complications often begins shortly after beginning therapy. The OIG should further investigate the clinical rationales for switching medications, i.e., whether the reports of clinical complications truly reflect complications such as irregular heartbeat, increased tolerance, or loss of efficacy or whether payment issues were also involved.
- 5) The OIG also found that for a small number of beneficiaries, medications were changed without the knowledge of the physician. While Federal oversight of physician prescribing is limited, we find it disturbing that suppliers may change medication without informing the physician, especially in light of the physician responses regarding possible clinical complications associated with the use of a drug. The OIG should further investigate these suppliers and physicians in order to determine if the medication change was appropriate under State pharmacy laws and if the physicians would have agreed to make the medication changes had they known.

We appreciate the OIG's continuing monitoring of the Medicare Part B drug markets and look forward to working with the OIG in future endeavors.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

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