

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PART B PAYMENTS FOR DRUGS
INFUSED THROUGH DURABLE
MEDICAL EQUIPMENT**



Daniel R. Levinson
Inspector General

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OEI-12-12-00310

**EXECUTIVE SUMMARY: PART B PAYMENTS FOR DRUGS INFUSED THROUGH DURABLE MEDICAL EQUIPMENT
OEI-12-12-00310**

WHY WE DID THIS STUDY

Medicare pays 106 percent of the average sales price (ASP) for most drugs covered under Part B. However, payment amounts for infusion drugs administered in conjunction with durable medical equipment (DME) are instead set at 95 percent of the drugs' average wholesale prices (AWP) that were in effect on October 1, 2003. Numerous Office of Inspector General reports have shown that AWP greatly exceed drug acquisition costs. Basing payments for DME infusion drugs on AWP set almost a decade ago raises concerns about whether Medicare payment levels are appropriate.

HOW WE DID THIS STUDY

For every year between 2005 and 2011, we compared the ASP (which serves as an estimate for provider acquisition cost) of each DME infusion drug to its AWP-based Medicare payment amount. ASPs are statutorily defined and based on actual sales data. We also calculated how much Medicare would have saved between 2005 and 2011 had payment been based on ASPs rather than AWP.

WHAT WE FOUND

Overall, Medicare payment amounts for DME infusion drugs exceeded ASPs by 54 to 122 percent annually. Most individual drugs had Medicare payment amounts that exceeded ASPs, many by more than two times, in each year. However, for as many as one-third of DME infusion drugs in each year, the payment amounts were below their ASPs, meaning that Medicare may be underpaying providers for these drugs. Medicare spending on DME infusion drugs would have been reduced by 44 percent (\$334 million) between 2005 and 2011 had payment been based on ASPs.

WHAT WE RECOMMEND

Our results once again show that AWP are unrelated to actual prices in the marketplace and that the reliance on an AWP-based payment methodology has cost Medicare hundreds of millions of dollars. Therefore, we recommend that the Centers for Medicare & Medicaid Services (CMS) either (1) seek a legislative change requiring DME infusion drugs to be paid using the ASP methodology or (2) include DME infusion drugs in the next round of the competitive bidding program. CMS partially concurred with the recommendation to seek a legislative change and concurred with the recommendation to include DME infusion drugs in the next round of the competitive bidding program.

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OBJECTIVES

1. To compare Medicare payment amounts based on average wholesale prices (AWP) to average sales prices (ASP) for Part B durable medical equipment (DME) infusion drugs between 2005 and 2011.
2. To determine how much Medicare would have saved on DME infusion drugs between 2005 and 2011 had payment been based on the ASP methodology.

BACKGROUND

Infusion drugs administered in conjunction with DME are one of the few types of drugs that are paid by Medicare Part B using AWP instead of ASPs. Numerous Office of Inspector General (OIG) reports have found that AWP often greatly exceed the drugs' actual costs. Partly on the basis of this work, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) replaced AWP with ASP—a benchmark that reflects actual prices in the marketplace—as the pricing method for most Part B drugs beginning on January 1, 2005.¹ However, the MMA excluded infusion drugs used with DME from the new ASP methodology and set their payment amount at 95 percent of the AWP that were in effect on October 1, 2003.²

Medicare Part B Coverage of Infusion Pumps

In infusion therapy, drugs are typically administered intravenously using a needle, catheter, or device such as an infusion pump to control the rate of drug flow.³ Physicians often prescribe infusion therapy when oral medications may not effectively treat the patient's condition.⁴ Infusion therapy is commonly used to treat acute conditions, such as pain and infections, and chronic conditions, such as cancer, multiple sclerosis, and rheumatoid arthritis.⁵ Infusion therapy is often provided in the home rather than in inpatient settings to reduce costs associated with inpatient care and maintain patient convenience and comfort.⁶

In general, external and implantable pumps used in infusion therapy are covered by Medicare under the DME benefit when they are used as

¹ MMA, P.L. 108-173, § 303(c) (adding section 1847A of the Social Security Act (the Act)).

² MMA, P.L. 108-173, § 303(b) (amending section 1842(o)(1) to set a different payment methodology for infusion drugs administered through DME at 1842(o)(1)(D)(i)).

³ National Home Infusion Association (NHIA), *Infusion FAQs*. Accessed at <http://www.nhia.org> on July 18, 2012.

⁴ NHIA, *About Infusion Therapy*. Accessed at <http://www.nhia.org> on July 18, 2012.

⁵ NHIA, *Infusion FAQs*. Accessed at <http://www.nhia.org> on July 18, 2012.

⁶ *Ibid.*

specified by the *Medicare National Coverage Determinations Manual*. For example, Medicare covers external infusion pumps when used to treat iron poisoning, thromboembolic disease, and diabetes, among other conditions. Implantable infusion pumps are covered when they are used to treat certain conditions, including chronic intractable pain, chronic intractable spasticity, and liver cancer.⁷

Medicare Part B Coverage of DME Infusion Drugs

Part B-covered drugs generally fall into the following categories: drugs furnished incident to a physician's service (e.g., injectable drugs used in connection with the treatment of cancer); drugs explicitly covered by statute (e.g., some vaccines and oral anticancer drugs); and drugs used in conjunction with DME (e.g., certain inhalation and infusion drugs).^{8, 9}

Medicare Part B covers drugs used in infusion therapy under its DME benefit if (1) the drug is necessary for the effective use of a covered external or implantable infusion pump and (2) the drug being used with the pump is itself reasonable and necessary for the patient's treatment.¹⁰ From 2005 to 2011, the Centers for Medicare & Medicaid Services (CMS) classified 31 to 38 drugs as "DME infusion" in any given quarter.¹¹

Medicare Part B Payments for DME Infusion Drugs

CMS pays physicians and DME suppliers for most Part B-covered drugs using a methodology based on ASPs. Section 1847A(c) of the Act defines ASP as a manufacturer's sales of a drug (with certain exceptions) 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. The ASP is net of any price concessions, such as volume discounts, "prompt pay" discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. As such, it can be considered a proxy for providers' acquisition costs. Manufacturers provide CMS with the ASPs and volume of sales for each of their drug products on a quarterly basis, with submissions due 30 days after the close of each quarter. Medicare payments for most Part B-covered prescription drugs are equal to 106 percent of the volume-weighted ASPs for the HCPCS

⁷ *Medicare National Coverage Determinations Manual*, ch. 1 § 280.14.

⁸ Infusion drugs used in conjunction with DME will hereinafter be referred to as "DME infusion drugs."

⁹ 42 CFR § 414.900(b) and *Medicare Benefit Policy Manual*, ch. 15 § 50.

¹⁰ *Medicare National Coverage Determinations Manual*, ch. 1 § 280.14.

¹¹ DME infusion drugs are classified and paid using Healthcare Common Procedure Coding System (HCPCS) codes. In the case of prescription drugs, each HCPCS code defines the drug name and the amount of drug represented by the HCPCS code but does not specify manufacturer or package size information.

code (or the actual billed charge, if that amount is lower). Medicare beneficiaries are responsible for 20 percent of this amount in coinsurance, as well as for any deductible.

Unlike most drugs covered under Part B, DME infusion drugs are not paid on the basis of ASPs. Rather, section 1842(o)(1)(D)(i) of the Act, as amended by the MMA, sets payment amounts for these drugs at 95 percent of the AWP that were in effect on October 1, 2003.¹² Statutes and regulations do not define AWP, and AWP does not represent actual transactional prices. Rather, AWP is the list price established by drug manufacturers and reported by publishers such as Red Book.

For a single-source DME infusion drug, the Part B payment amount for a HCPCS code is based on 95 percent of the drug's AWP on October 1, 2003.¹³ For a multiple-source DME infusion drug, payment is based on 95 percent of the median AWP on October 1, 2003, for generic sources. However, if the lowest AWP among brand-name products is less than the generic sources' median AWP, Medicare pays 95 percent of this brand-name product's AWP. Each quarter, CMS publishes on its Web site the AWP-based payment amounts for DME infusion drugs.¹⁴ Medicare beneficiaries are responsible for 20 percent of the payment amount in coinsurance, as well as for any deductible.

In 2011, Medicare and its beneficiaries spent approximately \$125 million for 21 DME infusion drugs. (The other 10 drugs classified as "DME infusion" were not associated with any Part B expenditures.) However, just 3 of the 21 drugs accounted for 91 percent of expenditures, with a single drug (milrinone lactate) accounting for 62 percent of the total.^{15, 16}

Competitive Bidding for DME Infusion Drugs

The DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program was mandated by section 302 of the MMA to reduce

¹² According to section 20.1.3 of chapter 17 of the *Medicare Claims Processing Manual*, this payment methodology does not apply if the drug is compounded or furnished incident to a professional service. Also, pursuant to section 1842(o)(1)(D)(ii) of the Act, payments for DME infusion drugs are not based on 95 percent of AWP if furnished in competitive bidding areas. However, CMS is implementing the competitive bidding program by phasing in specific items. *Medicare Claims Processing Manual*, ch. 36 § 20.1. At this time, DME infusion drugs have not been designated for inclusion in the competitive bidding program.

¹³ *Medicare Claims Processing Manual*, ch. 17 § 20.4.

¹⁴ Although the payment amounts remain constant, the HCPCS codes classified as DME infusion and thus subject to AWP-based payment may change from quarter to quarter.

¹⁵ 2011 National Claims History (NCH) DME file. Claims data are added to NCH files on a rolling basis. Therefore, the 2011 NCH DME file did not include 100 percent of claims for DME infusion drugs when OIG analyzed it in April 2012.

¹⁶ Milrinone lactate (brand name Primacor) is used to treat congestive heart failure.

expenses for Medicare and its beneficiaries.¹⁷ DME suppliers submit bids to become Medicare contract suppliers and to furnish items in competitive bidding areas. Payment amounts resulting from the bids replace current fee-schedule payment amounts for the items.¹⁸ The competitive bidding program has been implemented in phases beginning with bids for items with the highest cost and highest volume or with the largest savings potential.¹⁹ On January 1, 2011, CMS launched the initial phase in nine geographic areas for nine product categories.²⁰ Pursuant to the Patient Protection and Affordable Care Act, all areas will have competitive bidding or payment rate adjustments based on competitive bid rates by 2016.²¹ At this time, DME infusion drugs have not been included as part of the competitive bidding process. According to CMS staff, the agency intends to include DME infusion drugs in a future phase of the program; however, no definitive plans for their inclusion have been announced.

Previous OIG Work

Since 1997, OIG has released numerous reports showing that AWP greatly exceed acquisition costs. For example, a 2001 OIG report found that Part B payment amounts, which were set at 95 percent of AWP, exceeded actual wholesale prices (obtained from wholesaler catalogs) for 24 drugs with the highest total Medicare payments.²² If Medicare had reimbursed these drugs at the actual wholesale prices, it would have saved \$761 million a year. Another OIG report found that Medicare payments for end stage renal disease drugs, which were set at 95 percent of AWP, exceeded amounts paid by the Department of Veterans Affairs (VA) in 1999.²³ Medicare Part B payment amounts would have been nearly halved for five drugs had payment amounts been based on VA acquisition costs. Both of these studies recommended that CMS reduce excessive Medicare payment amounts.

¹⁷ *Medicare Claims Processing Manual*, ch. 36 § 10.

¹⁸ *Ibid.*

¹⁹ *Medicare Claims Processing Manual*, ch. 36 § 20.1.

²⁰ CMS, *DMEPOS Competitive Bidding*. Accessed at <https://www.cms.gov> on July 12, 2012.

²¹ The Patient Protection and Affordable Care Act, P.L. 111-148 § 6410.

²² OIG, *Medicare Reimbursement of Prescription Drugs*, OEI-03-00-00310, January 2001.

²³ OIG, *Medicare Reimbursement of End Stage Renal Disease Drugs*, OEI-03-00-00020, June 2000.

METHODOLOGY

Data Collection

Selection of Drugs. We used CMS’s payment amount files to select the HCPCS codes that were paid on the basis of DME infusion payment limits (i.e., 95 percent of AWP from October 1, 2003) in each quarter between 2005 and 2011. As previously stated, during that time, 31 to 38 HCPCS codes were classified as “DME infusion drugs” in any given quarter. See Appendix A for a list of these drugs.

Total Part B Expenditures and Utilization for DME Infusion Drugs. We obtained all paid Part B DME claims for infusion drug HCPCS codes from the 2005–2011 NCH DME files to determine quarterly utilization and spending. If a HCPCS code did not have any associated expenditures in a particular quarter, we removed the code from the analysis for that quarter (i.e., our analysis includes only codes for which there were Part B expenditures). As a result, between 7 and 13 HCPCS codes were removed from our analysis in any given quarter.

AWP-Based Payment Amounts. We obtained the AWP-based payment amounts for all relevant HCPCS codes in every quarter between 2005 and 2011 from CMS’s payment amount files.

ASPs and ASP-Based Payment Amounts. CMS also calculates ASP-based payment amounts for the HCPCS codes under review for situations when the drugs are provided incident to a professional service (e.g., the identical drug is paid on the basis of its ASP rather than AWP when it is administered in a physician’s office rather than infused in a patient’s home).²⁴ We obtained the ASP-based payment amounts for all relevant HCPCS codes in every quarter under review from CMS’s payment amount files. We used the ASP-based payment amounts to calculate ASPs by dividing each HCPCS code’s ASP-based payment amount by 1.06.²⁵ As previously stated, because ASPs are based on actual sales in the marketplace, they provide a reasonable estimate of the acquisition costs of these drugs for providers.

²⁴ *Medicare Claims Processing Manual*, ch. 17 § 20.1.3.

²⁵ There is a two-quarter lag between the time when ASP sales occur and when Medicare payment amounts reflect those sales. As a result, ASPs in a given quarter were calculated using ASP-based payment amounts from two quarters later (e.g., fourth-quarter 2011 ASPs were calculated by dividing second-quarter 2012 payment amounts by 1.06). We removed between zero and four HCPCS codes from our comparisons in any given quarter because there were no ASP-based payment data in the relevant quarter on which to base our calculations.

Data Analysis

Comparing ASPs and Medicare Payment Amounts Between 2005 and 2011. We first estimated an annual ASP for each HCPCS code by weighting the ASP in each quarter by Part B utilization in that quarter. We then calculated the difference between the AWP-based payment amount and the annual ASP for each HCPCS code. For every year from 2005 through 2011, we counted the number of DME infusion drug HCPCS codes that had Medicare payment amounts that exceeded their annual ASPs and the number of codes with Medicare payment amounts that were less than their annual ASPs. We examined whether the number of HCPCS codes with Medicare payments amounts above and below their annual ASPs changed during this period.

To determine an *overall* difference between Medicare payment amounts and ASPs across all DME infusion drugs in each year, we calculated a median difference among all the individual HCPCS codes. We tracked these median differences over the entire 2005–2011 period to determine whether the relationship between ASPs and Medicare payment amounts changed across the entire group of DME infusion drugs during this time.

Determination of Potential Savings. For each HCPCS code, we multiplied its utilization by its ASP-based payment amount for every quarter between 2005 and 2011 to determine how much would have been spent if payments for DME infusion drugs had been set at 106 percent of ASP (i.e., the methodology used to pay for most Part B drugs). We then subtracted the result from actual expenditures in the relevant quarter to determine the difference in spending between the AWP-based and ASP-based payment methodologies. We added the quarterly results to determine the total savings in each year from 2005 to 2011.

Limitations

We did not review Part B claims for accuracy, nor did we review any documentation in support of the claims included in our study. We also did not examine any infusion-related services (either covered or uncovered) that may have been provided to beneficiaries who received DME infusion drugs.

Standards

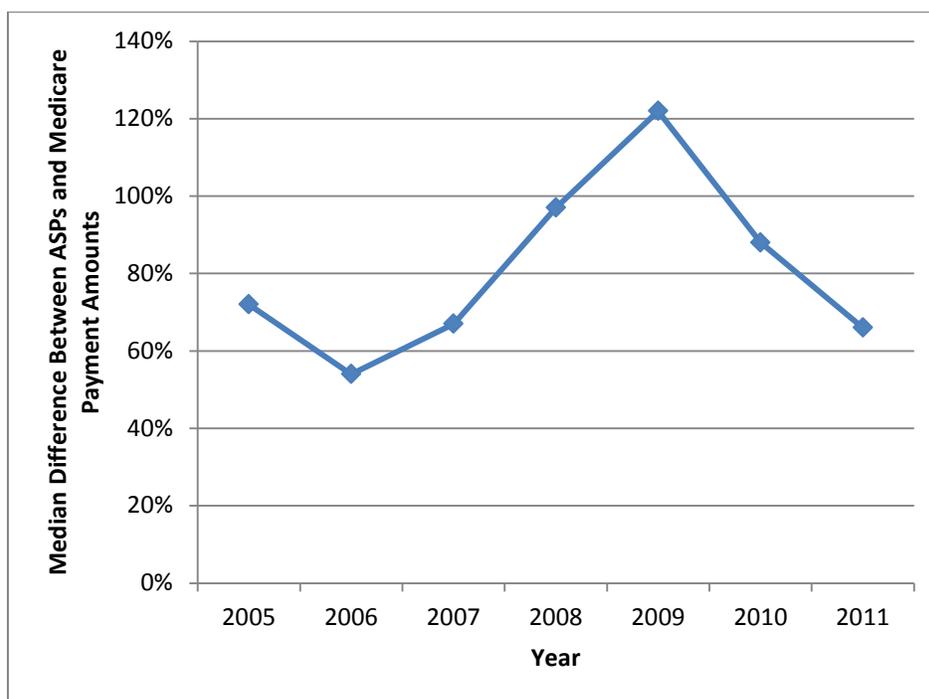
This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Overall, Medicare payment amounts for DME infusion drugs exceeded ASPs by 54 to 122 percent annually from 2005 to 2011

Given that ASPs should reflect providers' acquisition costs, our analysis suggests that Medicare overpaid for DME infusion drugs by a substantial margin in each year from 2005 to 2011. Although overall differences were smallest in 2006, Medicare payment amounts that year still exceeded ASPs by 54 percent at the median (see Figure 1). In contrast, the largest spread was in 2009, when payment amounts were more than double the ASPs at the median.

Figure 1: Median Difference Between ASPs and Medicare Payment Amounts From 2005–2011 for All DME Infusion Drugs



Source: OIG analysis of CMS's 2005–2011 payment amount files.

From 2005 to 2011, the majority of drugs had Medicare payment amounts that exceeded ASPs; however, as many as one-third of drugs had payment amounts that were less than ASPs each year, meaning that providers were potentially being underpaid for some products

In each year under review, 67 to 86 percent of DME infusion drug HCPCS codes had Medicare payment amounts that exceeded their ASPs (see Table 1). In many of these cases (between 46 and 52 percent each year),

Medicare paid providers at rates that were more than double the ASPs of the drugs. For example, in 2011, 10 of the 21 HCPCS codes for DME infusion drugs had AWP-based payment amounts that were at least twice the ASPs, with 4 of these being paid at more than 10 times the market prices.

In contrast, from 2005 to 2011, 14 to 33 percent of HCPCS codes (as many as 7 drugs per year) had ASPs that exceeded their Medicare payment amounts. In other words, Medicare reimbursement may not have been sufficient to cover the average cost of these drugs, possibly because payment amounts had remained unchanged since 2003. For example, in 2005, the annual ASP of the drug ganciclovir sodium was \$34.33 and Medicare paid providers \$35.25 (a spread of 3 percent).²⁶ The following year, the annual ASP of the drug increased to \$36.78 but the Medicare payment amount stayed the same. By 2011, the ASP of ganciclovir sodium had risen to \$65.03, yet Medicare payment was still \$35.25 (or 46 percent below ASP).

Table 1: Percentage of Drugs With Medicare Payment Amounts Greater and Less Than ASPs

| | 2005 n=29 | 2006 n=24 | 2007 n=26 | 2008 n=26 | 2009 n=23 | 2010 n=23 | 2011 n=21 |
|------------------------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| Payment is greater than ASP | 86% | 79% | 73% | 73% | 70% | 74% | 67% |
| Payment is less than ASP | 14% | 21% | 27% | 27% | 30% | 26% | 33% |

Source: OIG analysis of CMS's 2005–2011 payment amount files.

The DME infusion drug with the highest expenditures in each of the last 6 years had Medicare payment amounts that were 10 to 18 times greater than ASPs

In every year under review except 2005, Medicare spent more on milrinone lactate than on any other DME infusion drug. From 2005 to 2011, expenditures for milrinone lactate accounted for 24 to 62 percent of total yearly spending in the DME infusion category, despite the fact that only a small percentage of providers supplied the drug. For example, in

²⁶ Ganciclovir sodium (brand name Cytovene) is an antiviral drug.

2011, just 5 percent of infusion drug providers had paid Part B claims for milrinone lactate.²⁷

In 5 of the 7 years, milrinone lactate also had the greatest difference between Medicare payment amounts and ASPs among all DME infusion drugs. For example, in 2006, the annual ASP was \$2.80 for milrinone lactate, while the AWP-based payment amount was more than 18 times greater (\$51.58).²⁸ In 2011, despite an increase in ASP (to \$4.32 on average), Medicare was still paying almost 12 times the ASP.²⁹

Medicare and its beneficiaries would have saved \$334 million between 2005 and 2011 if payments for DME infusion drugs had been based on ASPs

If payment amounts for DME infusion drugs had been based on ASPs rather than AWPs between 2005 and 2011, total Medicare Part B spending would have been reduced by 44 percent (from \$765 million to \$431 million), a savings of \$334 million. One-fifth of the savings (\$67 million) would have been realized by beneficiaries in the form of reduced coinsurance. Figure 2 shows the spending under the two methodologies each year.

Potential savings based on the ASP methodology ranged from 28 percent in 2005 to 57 percent in 2011. Reduced payments for milrinone lactate would have accounted for more than three-quarters of the savings in each year. For example, in 2011, Medicare payments to just 263 providers for milrinone lactate would have been reduced by almost \$71 million (or nearly 99 percent of the total savings for all DME infusion drugs) had reimbursement been set at 106 percent of ASP.

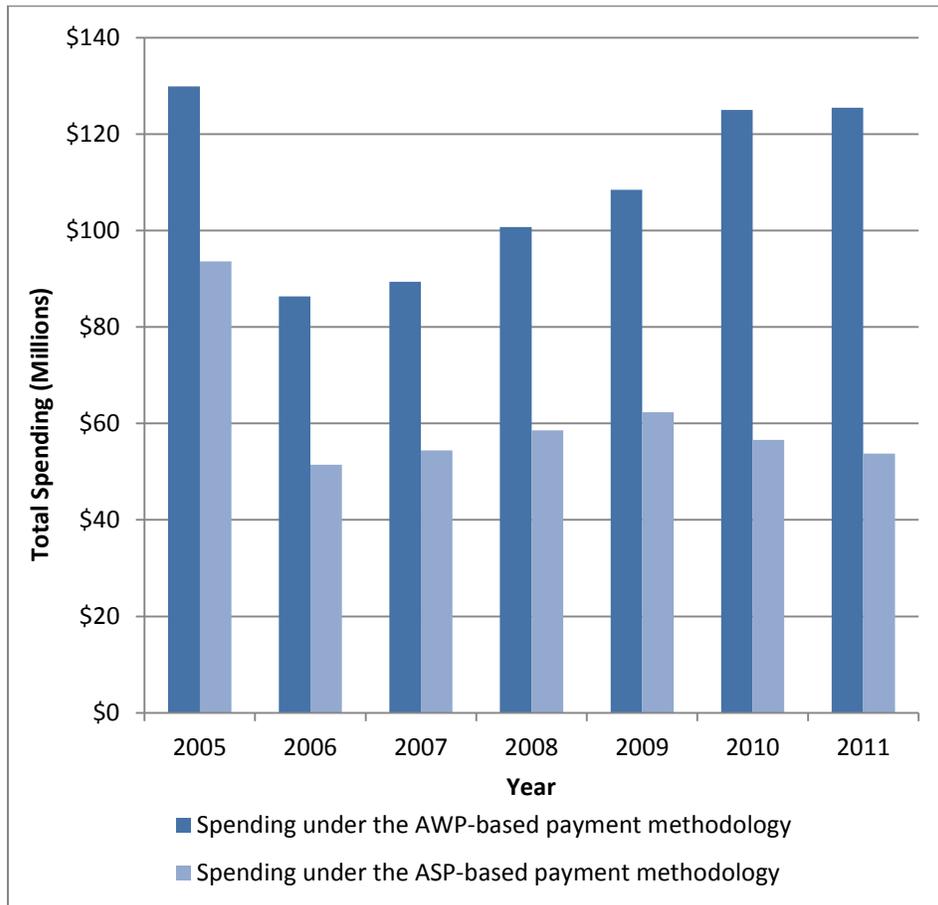
Payment amounts for most drugs would have decreased under the ASP methodology. However, because the ASP-based payment amounts for some drugs were higher than the existing AWP-based payment amounts (i.e., providers were likely being underpaid), Medicare spending would have actually increased for some drugs. For example, in 2011, Medicare spending would have been reduced by \$76 million for 14 drug codes but would have increased by \$4 million for 7 drug codes, resulting in a net savings of \$72 million.

²⁷ Of the 4,995 providers that had paid Part B claims for DME infusion drugs in 2011, only 263 had paid claims for milrinone lactate.

²⁸ The next highest spread was for bleomycin sulfate, at almost nine times the ASP.

²⁹ However, milrinone lactate no longer had the largest spread.

Figure 2: Medicare Part B Spending for DME Infusion Drugs Under AWP-Based and ASP-Based Methodologies From 2005–2011



Note: Medicare spending includes beneficiary copayments and deductibles.

Source: OIG analysis of CMS's 2005–2011 payment amount files.

CONCLUSION AND RECOMMENDATIONS

Unlike most drugs covered under Medicare Part B, DME infusion drugs are still being paid under a flawed AWP-based reimbursement methodology. Our findings—like those of OIG’s previous studies in this area—demonstrate that AWPs are unrelated to the prices of drugs in the marketplace and that the reliance on an AWP-based payment methodology has cost the program hundreds of millions of dollars.

Furthermore, although the current methodology has led to excessive payments to providers for most DME infusion drugs, we also found that providers may actually be paid below their costs for a number of DME infusion drugs. These payment-related issues could significantly affect drug utilization and acquisition. For example, excessive payments could present incentives for providers to overutilize a particular product, while payments that are below cost could contribute to an inability or unwillingness to provide a particular drug.

To ensure that payment amounts for DME infusion drugs more accurately reflect acquisition costs, we recommend that CMS either:

Seek a legislative change requiring DME infusion drugs to be paid using the ASP methodology

ASPs, which are based on actual sales and reported quarterly, are much more closely related to prices in the marketplace than AWPs set nearly a decade ago. In 2011 alone, Medicare would have saved \$72 million had it reimbursed on the basis of the ASP methodology.

Include DME infusion drugs in the next round of competitive bidding

The purpose of the DMEPOS competitive bidding program is to align Medicare payments with acquisition costs and ensure that providers will still be able to acquire items necessary to treat beneficiaries. CMS has noted that it intends to include DME infusion drugs in future competitive bidding efforts; however, no definitive plans for their inclusion have been announced. Given the payment issues discussed in this report, DME infusion drugs seem to be a prime candidate to be included sooner rather than later.

AGENCY COMMENTS

In its comments on the draft report, CMS partially concurred with the recommendation to seek a legislative change that would require DME infusion drugs to be paid using the ASP payment methodology. The agency noted that section 1842(o)(1)(D) of the Social Security Act would need to be amended and the request for legislative change would need to be included in the annual President's Budget.

CMS concurred with the recommendation to include DME infusion drugs in the next round of the DMEPOS competitive bidding program. CMS stated that it plans to include infusion drugs in a future round of the program.

CMS also provided several technical comments. In response, we made minor revisions to the report, where appropriate. CMS's comments are provided in Appendix C.

APPENDIX A

Durable Medical Equipment Infusion Drug Descriptions

| Healthcare Common Procedure Coding System (HCPCS) Code | Description | HCPCS Code Dosage |
|--|--|-------------------|
| J0285 | Amphotericin b injection | 50 mg |
| J0287 | Amphotericin b lipid complex injection | 10 mg |
| J0288 | Amphotericin b cholesteryl sulfate complex injection | 10 mg |
| J0289 | Amphotericin b liposome injection | 10 mg |
| J0475 | Baclofen injection | 10 mg |
| J0476 | Baclofen intrathecal trial injection | 50 mcg |
| J0735 | Clonidine hydrochloride injection | 1 mg |
| J0895 | Deferoxamine mesylate injection | 500 mg |
| J1170 | Hydromorphone injection | 4 mg |
| J1230 | Methadone injection | 10 mg |
| J1250 | Dobutamine hydrochloride injection | 250 mg |
| J1325 | Epoprostenol injection | .5 mg |
| J1455 | Foscarnet sodium injection | 1000 mg |
| J1570 | Ganciclovir sodium injection | 500 mg |
| J1817 | Insulin for insulin pump use | 50 units |
| J2175 | Meperidine hydrochloride injection | 100 mg |
| J2260 | Milrinone lactate injection | 5 mg |
| J2270 | Morphine sulfate injection | 10 mg |
| J2271 | Morphine sulfate injection | 100 mg |
| J2275 | Morphine sulfate injection | 10 mg |
| J3010 | Fentanyl citrate injection | .1 mg |
| J9001 | Doxorubicin hydrochloride liposome injection | 10 mg |
| J9040 | Bleomycin sulfate injection | 15 units |
| J9065 | Cladribine injection | 1 mg |
| J9100 | Cytarabine hydrochloride injection | 100 mg |
| J9110 | Cytarabine hydrochloride injection | 500 mg |
| J9190 | Fluorouracil injection | 500 mg |
| J9200 | Floxuridine injection | 500 mg |
| J9208 | Ifosfamide injection | 1 gm |
| J9280 | Mitomycin injection | 5 mg |

| HCPCS Code | Description | HCPCS Code Dosage |
|-------------------|----------------------------------|--------------------------|
| J9355 | Trastuzumab injection | 10 mg |
| J9360 | Vinblastine sulfate injection | 1 mg |
| J9370 | Vincristine sulfate injection | 1 mg |
| J9375 | Vincristine sulfate injection | 2 mg |
| J9380 | Vincristine sulfate injection | 5 mg |
| Q4075* | Acyclovir injection | 5 mg |
| Q4076* | Dopamine hydrochloride injection | 40 mg |
| Q4077* | Treprostinil injection | 1 mg |

Note: The Centers for Medicare & Medicaid Services (CMS) did not classify all of the listed drugs as durable medical equipment infusion drugs in every quarter between 2005 and 2011.

*HCPCS codes Q4075, Q4076, and Q4077 were deleted as of December 31, 2005. They were replaced with HCPCS codes J0133, J1265, and J3285, respectively, as of January 1, 2006, and were no longer subject to the DME infusion payment limit during the subsequent quarters under review.

Source: CMS's 2005–2011 payment amount files.

APPENDIX B

Annual Savings Under the Average Sales Price Methodology

| Year | Total Spending for Durable Medical Equipment (DME) Infusion Drugs | Spending Under Average Sales Price (ASP)-Based Methodology | Savings Under ASP-Based Payment Methodology | Percentage Savings Under ASP-Based Payment Methodology |
|--------------|---|--|---|--|
| 2005 | \$129,917,517 | \$93,627,954 | \$36,289,563 | 28% |
| 2006 | \$86,313,154 | \$51,464,796 | \$34,848,358 | 40% |
| 2007 | \$89,365,108 | \$54,438,177 | \$34,926,931 | 39% |
| 2008 | \$100,700,741 | \$58,574,188 | \$42,126,553 | 42% |
| 2009 | \$108,419,875 | \$62,306,379 | \$46,113,495 | 43% |
| 2010 | \$124,990,747 | \$56,573,383 | \$68,417,364 | 55% |
| 2011 | \$125,459,122 | \$53,732,067 | \$71,727,055 | 57% |
| Total | \$765,166,263 | \$430,716,945 | \$334,449,318 | 44% |

Source: Office of Inspector General (OIG) analysis of the Centers for Medicare & Medicaid Services' 2005–2011 payment amount files and OIG analysis of 2005-2011 National Claims History DME files.

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

DATE: DEC 17 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: "Part B Payments for Drugs Infused through Durable Medical Equipment" (OEI-12-12-00310)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and respond to the OIG Draft Report titled, "*Part B Payments for Drugs Infused Through Durable Medical Equipment*" (OEI-12-12-00310).

The OIG's objectives were to compare Medicare payment amounts based on average wholesale prices (AWP) to average sales prices (ASP) for Part B durable medical equipment (DME) infusion drugs between 2005 and 2011; and determine how much Medicare would have saved on DME infusion drugs between 2005 and 2011 had payment been based on the ASP methodology.

The OIG found that during each year between 2005 and 2011 the payment amounts for 67 to 86 percent of health care common procedure codes (HCPCS) identified by OIG as DME infusion drugs exceeded ASP by a substantial margin. The report also noted that as many as one third of the payment amounts were significantly less than ASP. Overall, the potential savings associated with using ASP-based payments instead of AWP-based payments ranged from 28 percent in 2005 to 57 percent in 2011. The savings estimate totaled \$334 million for the period 2005 to 2011. One drug, milrinone-anagent infused for the treatment of congestive heart failure, accounted for about three quarters of the potential savings for each year.

OIG Recommendation

CMS should revise payments for DME infusion drugs to reflect acquisition costs by either seeking a legislative change to pay infusion drugs under the same payment methodology as other Part B drugs (i.e., 106 percent of ASP) or including infusion drugs in the next round of the DME competitive bidding program.

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CMS Response

CMS partially concurs with the recommendation to seek a legislative change. Section 1842(o)(1)(D) of the Social Security Act requires that the payment amount “in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, is 95 percent of the average wholesale price for such a drug in effect on October 1, 2003.” A legislative change amending this section would be needed to revise the payment methodology for DME infusion drugs. Any request for legislative change of Agency policies would be included in the annual President’s Budget.

CMS concurs with the recommendation to include DME infusion drugs in the next round of the DME competitive bidding program. Section 1847(a)(2)(A) of the Social Security Act mandates that competitive bidding programs be implemented for DME including items used in infusion and drugs. Competitive bidding for furnishing external infusion pumps and supplies in the nine Round 1 competitive bidding areas is currently underway. Although we did not phase in infusion drugs as part of this round of competitive bidding, we plan to phase in infusion drugs as part of a future round.

Attached please find a few technical comments on the report. CMS thanks OIG for its efforts on this draft report and looks forward to working with OIG in the future.

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Bahar Adili served as the lead analyst for this study. Central office staff who provided support include Berivan Demir Neubert, Kevin Farber, Scott Manley, and Christine Moritz.

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