



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



TO: Andrew M. Slavitt APR 21 2015
Acting Administrator
Centers for Medicare & Medicaid Services

/S/

FROM: Suzanne Murrin
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SUBJECT: Recommendation Followup Memorandum Report: *Implementing OIG Recommendation Could Have Reduced Payments for DME Infusion Drugs by Hundreds of Millions of Dollars*, OEI-12-15-00110

This memorandum report estimates (1) the amount by which Medicare expenditures for infusion drugs administered in conjunction with durable medical equipment (DME) could have been reduced if the Part B payment methodology had been revised as previously recommended by the Office of Inspector General (OIG), and (2) the difference between acquisition costs and Medicare payment amounts for DME infusion drugs.

SUMMARY

A February 2013 OIG report found that overall, Medicare payment amounts for DME infusion drugs substantially exceeded estimated acquisition costs, and that paying on the basis of average sales prices (ASPs) rather than average wholesale prices (AWPs) would have reduced Medicare expenditures by hundreds of millions of dollars between 2005 and 2011. We recommended that the Centers for Medicare & Medicaid Services (CMS) either (1) seek a legislative change requiring DME infusion drugs to be paid using the ASP-based methodology or (2) include DME infusion drugs in the next round of the competitive bidding program. CMS partially concurred with the first recommendation, but has not taken steps toward seeking legislation. CMS concurred with the second recommendation but said subsequently that DME infusion drugs will not be included in competitive bidding until at least 2017.

In updating our analysis, we found that Medicare expenditures for DME infusion drugs could have been reduced by \$251 million in an 18-month period if the ASP-based payment methodology recommended by OIG had been implemented in April 2013 (i.e., the quarter after our earlier report was issued). Between the second quarter of 2013 and the third quarter of 2014,

at least 42 percent of DME infusion drugs had Medicare payment amounts that were more than twice their estimated acquisition costs. In contrast, approximately one-quarter of these drugs had payment amounts that were below costs.

BACKGROUND

Medicare Part B Coverage of Infusion Pumps and Related Drugs

In general, external and implantable pumps used in infusion therapy, as well as related drugs, are covered by Medicare under the DME benefit when they are used as specified by the *Medicare National Coverage Determinations Manual*.¹ Infusion therapy is often provided in the home rather than in inpatient settings to reduce costs associated with inpatient care and to maintain patient convenience and comfort.²

Medicare Part B Payments for DME Infusion Drugs

Medicare payment amounts for most Part B-covered prescription drugs are equal to 106 percent of the volume-weighted ASPs for the drugs.^{3, 4} However, DME infusion drugs are not paid on the basis of ASPs. Rather, payment amounts for these drugs are set at 95 percent of the AWP that were in effect on October 1, 2003.⁵ Statutes and regulations do not define AWP, and AWPs do not represent actual transactional prices. Rather, AWPs are the list prices established by drug manufacturers and reported by publishers such as Red Book. Prior OIG work found that AWP was a fundamentally flawed basis for reimbursing for drugs under Medicare Part B. Medicare beneficiaries are responsible for 20 percent of the payment amount in coinsurance, as well as for any deductible, regardless of whether payment is based on ASPs or AWPs.⁶

¹ *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1 § 280.14.

² National Home Infusion Association (NHIA), *Infusion FAQs*. Accessed at <http://www.nhia.org/faqs.cfm> on July 18, 2012.

³ Section 1847A(c) of the Social Security Act (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.

⁴ In general, Part B drugs are classified using Healthcare Common Procedure Coding System codes.

⁵ Section 1842(o)(1)(D)(i) of the Act. According to section 20.1.3 of chapter 17 of the *Medicare Claims Processing Manual*, Pub. No. 100-04, this methodology does not apply if the drug is compounded or furnished incident to a professional service. For DME infusion drugs not listed in compendia as of October 1, 2003, payments are set at 95 percent of their first published AWPs. 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 subject to competitive bidding.

⁶ Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). This mandatory payment reduction is applied after the beneficiary's coinsurance has been determined, resulting in a payment rate for most Part B drugs of 104.3 percent of the volume-weighted ASP. For further explanation, see CMS, "Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program—'Sequestration'," *CMS Medicare FFS Provider e-News*, March 8, 2013. Accessed at <http://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2013-03-08-standalone.pdf> on April 10, 2015.

Each quarter, CMS publishes on its Web site an ASP payment limit file that includes both ASP- and AWP-based payment amounts for most DME infusion drugs.⁷ However, CMS reported to OIG in September 2014 that the agency is not currently updating its list of DME infusion drugs, meaning that new infusion drugs do not have an AWP-based payment amount listed on CMS's payment limit files. The four Medicare Administrative Contractors (MACs) that process DME claims also publish lists of drugs (including DME infusion drugs) and payment amounts each quarter. Because payment amounts for DME infusion drugs are set using AWPs from 2003, they do not change from quarter to quarter. However, the actual number of drugs classified as DME infusion drugs may change each quarter and this number differs among the DME MACs.

From the second quarter of 2013 through the third quarter of 2014, Medicare Part B and its beneficiaries spent \$712 million for 31 DME infusion drugs.⁸ Expenditures for just six drugs accounted for 97 percent of this total.

Competitive Bidding for DME Infusion Drugs

The DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program was mandated by section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to reduce expenses for Medicare and its beneficiaries.⁹ DME suppliers submit bids to become Medicare contract suppliers and to furnish items in competitive bidding areas. Payment amounts resulting from the bids replace the fee-schedule payment amounts.¹⁰ Competitive bidding has been implemented in phases, beginning with bids for items with the highest cost and highest volume or for those with the largest savings potential.¹¹ At this time, DME infusion drugs have not been included as part of the competitive bidding process.

Previous OIG Report on DME Infusion Drugs

In February 2013, OIG released a report entitled *Part B Payments for Drugs Infused Through Durable Medical Equipment* (OEI-12-12-00310). We found that Part B payment amounts for DME infusion drugs listed on CMS's payment limit files exceeded estimated acquisition costs by 54 to 122 percent annually, and that Medicare spending on DME infusion drugs would have been reduced by \$334 million between 2005 and 2011 had payments been based on ASPs rather than AWPs. Furthermore, because Federal law requires payments to be based on AWPs from more than a decade ago, a number of DME infusion drugs had payment amounts that were below their ASPs, meaning that Medicare may be reimbursing providers at less than their cost for these drugs.

We recommended that CMS either (1) seek a legislative change requiring DME infusion drugs to be paid using the ASP-based methodology or (2) include DME infusion drugs in the next round of the competitive bidding program. CMS partially concurred with the first recommendation, but the agency has not taken steps toward seeking legislation. CMS concurred with the second

⁷ CMS also calculates ASP-based payment amounts for DME infusion drugs for situations when the drugs are provided incident to a professional service (e.g., the same drug is paid on the basis of its ASP rather than its AWP when it is administered in a physician's office rather than infused in a patient's home).

⁸ The total represents payments made by Medicare and beneficiaries (through coinsurance and deductibles).

⁹ *Medicare Claims Processing Manual*, ch. 36 § 10.

¹⁰ *Ibid.*

¹¹ *Medicare Claims Processing Manual*, ch. 36 § 20.1.

recommendation but subsequently said that DME infusion drugs will not be included in competitive bidding until at least 2017.

METHODOLOGY

Scope

This review focuses on Medicare payment amounts and ASPs for all DME infusion drugs from the second quarter of 2013 through the third quarter of 2014 (6 quarters in total). Our previous work included only drugs identified as “DME infusion” on CMS’s payment limit files. For this review, we expanded the scope by also including DME infusion drugs identified through an analysis of the four DME MACs’ payment limit files.

Data Collection and Analysis

Selection of Drugs. First, we used CMS’s payment limit files from the second quarter of 2013 through the third quarter of 2014 to identify all drugs with a DME infusion payment amount. In total, 28 DME infusion drugs were listed on CMS’s payment limit files in at least one of the quarters under review.

Unlike CMS’s files, which explicitly identify drugs that have DME infusion payment amounts, DME MAC files do not indicate whether a drug is categorized as such. We therefore analyzed the payment amounts on the quarterly DME MAC files to identify any drug for which the payment amount (1) did not change from quarter to quarter; (2) did not equal the ASP-based payment amount on the CMS payment file; and (3) did not vary among the individual DME MAC files. We then used product descriptions from CMS’s procedure code file and information from drug packaging labels to verify that the drug could be infused through DME. Our analysis of the DME MAC files identified an additional 22 drugs that were not listed as DME infusion on CMS’s payment limit files. In combining the list of drugs identified through our examination of CMS’s payment limit files and our analysis of DME MAC files, we identified a total of 50 DME infusion drugs for the period under review.

Total Part B Expenditures and Utilization for DME Infusion Drugs. We obtained all paid Part B DME claims for the 50 DME infusion drugs from the second quarter of 2013 through the third quarter of 2014.¹² If a drug did not have any associated expenditures in a particular quarter, we removed the code from the analysis for that quarter. As a result, between 21 and 23 drugs were removed from our analysis in any given quarter.

ASP- and AWP-Based Payment Amounts. We obtained from CMS’s payment limit files the ASP-based payment amounts for all DME infusion drugs in every quarter under review. Similarly, we obtained the AWP-based payment amounts for the same period from CMS’s payment limit files and the four DME MACs’ payment limit files.

¹² Expenditure data was extracted in October 2014 for dates of service between April 1, 2013, and September 30, 2014.

Estimated Acquisition Costs. Because ASPs are based on actual sales in the marketplace, they provide a reasonable estimate of the acquisition costs of drugs for providers. We used the ASP-based payment amounts to calculate ASPs in each quarter by dividing each drug's ASP-based payment amount by 1.06.¹³

Determination of Potential Savings. For each drug, we multiplied its utilization by its ASP-based payment amount in every quarter to determine how much Medicare and its beneficiaries would have spent if payments for DME infusion drugs had been set at 106 percent of ASP. 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 reduction in expenditures for the 6 quarters under review. To estimate how much beneficiaries' coinsurance would be reduced, we multiplied this total by 20 percent.

Comparing Medicare Payment Amounts and Estimated Acquisition Costs. For each quarter, we calculated the difference between the AWP-based payment amount and the estimated acquisition cost (i.e., the ASP) for each drug. We then counted the number of DME infusion drugs that had Medicare payment amounts that exceeded their estimated acquisition costs and the number of drugs with Medicare payment amounts that were less than their estimated acquisition costs. To determine an *overall* difference between Medicare payment amounts and estimated acquisition costs across all DME infusion drugs, we calculated a median difference among all the individual drugs in each quarter.

Limitations

We did not review Part B DME 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 that may have been provided to beneficiaries who received DME infusion drugs.

Under sequestration, the effective payment rate for Part B drugs (including DME infusion drugs) was reduced between 1 and 2 percent.¹⁴ Neither the published pricing data nor CMS expenditure data reflect these reductions. Our comparisons of acquisition costs and our estimates of savings in this report were calculated without regard to sequestration and therefore may be minimally overstated. In addition, our potential savings estimates are based on drug utilization under the current system; we did not estimate how a new payment methodology might change provider behavior and Medicare spending.

¹³ There is a 2-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 2 quarters later. We removed either one or three drugs from our comparisons in each quarter because there were no ASP-based payment amounts on which to base our calculations. In addition, in a small number of instances (once per quarter at most), a drug's ASP-based payment amount was set at 103 percent of the average manufacturer price rather than at 106 percent of the ASP. In these cases, we divided the payment amount by 1.03.

¹⁴ CMS, "Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program—'Sequestration'," *CMS Medicare FFS Provider e-News*, March 8, 2013. Accessed at <http://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2013-03-08-standalone.pdf> on April 10, 2015.

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.

RESULTS

Medicare expenditures for DME infusion drugs could have been reduced by \$251 million over just 6 quarters if the ASP-based payment methodology recommended by OIG had been implemented by April 2013

If payment amounts for DME infusion drugs had been based on ASPs rather than decade-old AWP between the second quarter of 2013 and the third quarter of 2014, total Medicare Part B spending would have decreased by 35 percent (from \$712 million to \$461 million), a reduction of \$251 million. Approximately one-fifth of this total (\$50 million) would have been realized by beneficiaries in the form of reduced coinsurance. Table 1 shows spending under the two methodologies and potential savings in each quarter had payments for DME infusion drugs been set at 106 percent of ASP as recommended by OIG.

Table 1: Potential Savings for DME Infusion Drugs Under the ASP-Based Methodology

Quarter	Actual Part B Expenditures*	Potential Expenditures at 106 Percent of ASP	Potential Savings at 106 Percent of ASP	Percentage Reduction
Q2 2013	\$125,321,855	\$83,664,076	\$41,657,780	33%
Q3 2013	\$132,846,997	\$86,766,567	\$46,080,430	35%
Q4 2013	\$128,519,744	\$81,581,528	\$46,938,216	37%
Q1 2014	\$115,002,267	\$74,883,495	\$40,118,772	35%
Q2 2014	\$119,160,403	\$77,168,028	\$41,992,375	35%
Q3 2014	\$91,476,968	\$56,996,730	\$34,480,238	38%
Total	\$712,328,235	\$461,060,424	\$251,267,812	35%

Source: OIG analysis of CMS and DME MAC payment files and CMS expenditure and utilization data.

Note: Totals may not equal the sums of the rows due to rounding. All figures include both the Medicare and beneficiary shares.

* Expenditure data was extracted in October 2014 for dates of service between April 1, 2013, and September 30, 2014.

Lowering payment amounts for just two of the three highest-expenditure drugs—milrinone lactate and Hizentra—would have led to \$267 million in reduced payments. During the 6 quarters under review, Medicare payments to 375 providers for milrinone lactate would have been reduced by almost \$166 million had reimbursement been set at 106 percent of ASP. Similarly, payments to 363 providers for Hizentra would have been reduced by \$101 million during the same time frame.

Because the ASP-based payment amounts for some drugs were higher than the existing AWP-based payment amounts, Medicare spending would have increased for some drugs. For example, Medicare spending would have increased by \$31 million for 9 drugs over the 6 quarters. However, Medicare spending would have been lowered by \$282 million for 21 other drugs, resulting in a net reduction of \$251 million.¹⁵

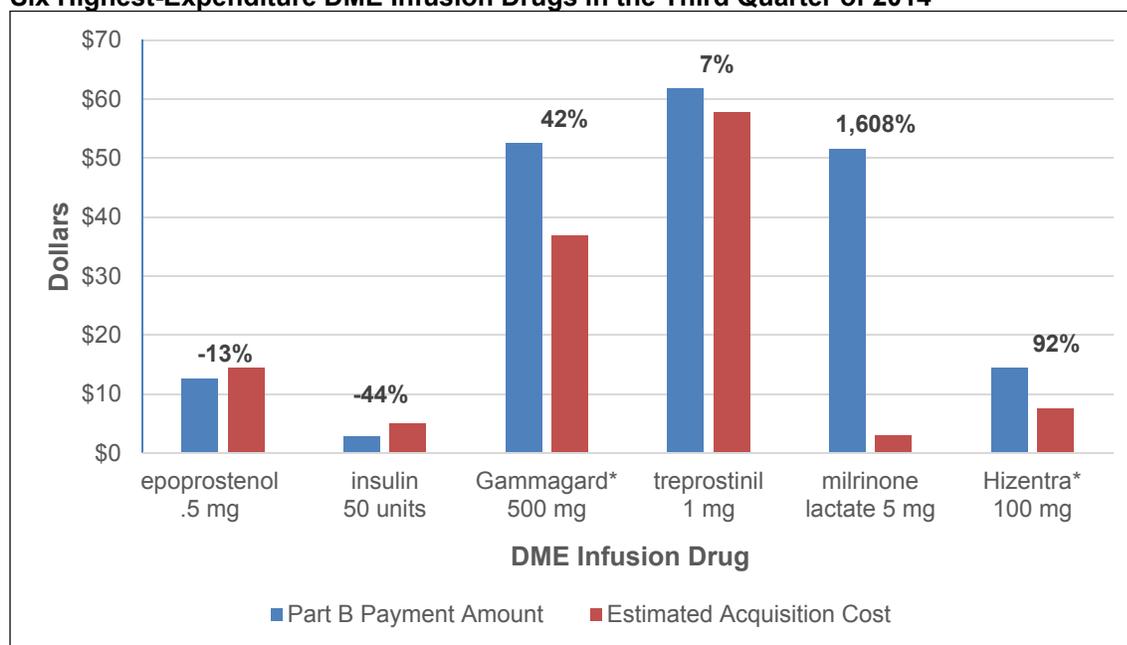
¹⁵ Medicare expenditures would have remained unchanged for one additional drug.

At least 42 percent of DME infusion drugs had Medicare payment amounts that were more than twice their estimated acquisition costs in each quarter

Our analysis indicates that again, Medicare paid providers substantially more than their costs for many DME infusion drugs. Overall, AWP-based payment amounts exceeded estimated acquisition costs by 35 to 85 percent, at the median, in each quarter. Among individual drugs, the quarterly AWP-based payment amounts were often more than twice the estimated acquisition costs.¹⁶ For example, the AWP-based payment amount for milrinone lactate has been set at \$51.58 for more than 10 years. However, during the period under review, the estimated acquisition cost of milrinone lactate ranged from \$2.44 to \$3.99, meaning that Medicare paid providers 13 to 21 times their estimated cost for the drug. On average, milrinone lactate providers each spent \$31,312 to acquire the drug during the 6 quarters, and were reimbursed \$475,330 for these purchases by Medicare, a net difference of almost \$450,000.

Figure 1 illustrates the disparity between Medicare payment amounts and provider acquisition costs for milrinone lactate and five other high-expenditure drugs that together accounted for 97 percent of Part B spending on DME infusion drugs.

Figure 1: Differences Between Part B Payment Amounts and Acquisition Costs for the Six Highest-Expenditure DME Infusion Drugs in the Third Quarter of 2014



Source: OIG analysis of CMS and DME MAC quarterly payment limit files and Part B claims data.

*Immune globulin.

Note: Negative percentages indicate that estimated acquisition costs are greater than Part B payment amounts.

¹⁶ Each quarter, between 42 percent and 46 percent of DME infusion drugs had Medicare payment amounts that were more than double their estimated acquisition costs.

Approximately one-quarter of DME infusion drugs had Medicare payment amounts that were below estimated acquisition costs

From the second quarter of 2013 through the third quarter of 2014, 71 to 75 percent of DME infusion drugs had Medicare payment amounts that exceeded their estimated acquisition costs. In contrast, 25 to 29 percent of drugs (as many as eight drugs per quarter) had Medicare payment amounts that were below their estimated costs, some by as much as 88 percent. In other words, Medicare reimbursement may not have been sufficient to cover the average cost of these drugs for providers, possibly because payment amounts have remained unchanged since 2003. For example, providers paid, on average, between \$5.01 and \$5.98 for 50 units of insulin (for use in an infusion pump) during the period under review. The Medicare payment amount, based on AWP from 2003, remained at \$2.80. As a result, providers who billed Medicare for insulin, which was one of the six highest-expenditure DME infusion drugs, may have been reimbursed at \$20 million below their total costs for purchasing the drug (50 percent) over these 6 quarters.

CONCLUSION

Our findings again illustrate that Medicare's payment methodology for DME infusion drugs, which relies on AWP published in 2003, has resulted in payments that bear little or no resemblance to provider acquisition costs. Under this methodology, providers are being reimbursed for many drugs at double their costs, while recouping only half of their costs for other drugs. OIG recommended in February 2013 that CMS seek a legislative change that would require DME infusion drugs to be paid under the same ASP-based methodology that is used for almost all other Part B drugs. If this legislative change had been enacted subsequent to OIG's recommendation, Medicare expenditures for DME infusion drugs could have been reduced by \$251 million over 18 months. These payment-related issues could also affect drug utilization. For example, payments that substantially exceed costs could present incentives for providers to overutilize a particular product, while payments that are below cost could contribute to providers' inability or unwillingness to provide a particular drug.

OIG continues to recommend that CMS seek a legislative change that would require payments for DME drugs to be based on ASPs. We recognize that seeking such a change through the legislative proposal process would not in itself change payments unless Congress chooses to enact this change. Therefore, we also continue to recommend that CMS use its existing authority to include DME infusion drugs in the competitive bidding program. We cannot predict exactly how competitive bidding would affect Medicare spending on DME infusion drugs; however, according to CMS, Phase 2 of competitive bidding has reduced Medicare payments for other DME by an average of 45 percent.¹⁷

This report contains no new recommendations and is thus being issued directly in final form. If you have comments or questions about this report, please do not hesitate to call me, or one of your staff may contact David Tawes, Regional Inspector General for Evaluation and Inspections,

¹⁷ CMS, *Round 2 Weighted Average Savings*. Accessed at [http://www.dmecompetitivebid.com/Palmetto/Cbcrd2.Nsf/files/R2_Weighted_Average_Savings.pdf/\\$File/R2_Weighted_Average_Savings.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbcrd2.Nsf/files/R2_Weighted_Average_Savings.pdf/$File/R2_Weighted_Average_Savings.pdf) on February 6, 2015.

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