

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE SUPPLIER
ACQUISITION COSTS FOR
L0631 BACK ORTHOSES**



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EXECUTIVE SUMMARY: MEDICARE SUPPLIER ACQUISITION COSTS FOR L0631 BACK ORTHOSES OEI-03-11-00600

WHY WE DID THIS STUDY

From 2008 to 2011, Medicare claims for L0631 back orthoses more than doubled, increasing Medicare allowances from \$36 million to more than \$96 million. Suppliers may bill Medicare for a variety of back orthosis products using code L0631, and the acquisition cost for each product may vary according to the manufacturer and model provided. However, Medicare does not collect information on the supplier acquisition costs or the models of L0631 back orthoses provided to beneficiaries. This study provides information on supplier acquisition costs for L0631 back orthoses that could assist the Centers for Medicare & Medicaid Services (CMS) in determining whether the Medicare payment amount is appropriate.

HOW WE DID THIS STUDY

From CMS's National Claims History file, we extracted Medicare claims for L0631 back orthoses with dates of service between July 1, 2010, and June 30, 2011. We randomly selected a sample of 350 suppliers and then randomly selected 1 claim from each. We requested that suppliers provide the acquisition cost of the L0631 orthoses they purchased for the claims, reflective of any discounts, rebates, fees, or charges. We also requested that suppliers describe the services they provided to beneficiaries, including fitting and adjustment services and instructions for using the orthoses.

WHAT WE FOUND

Medicare payment amounts were more than four times greater than supplier acquisition costs for L0631 back orthoses. Between July 2010 and June 2011, the average Medicare-allowed amount for L0631 back orthoses was \$919 and the average supplier acquisition cost was \$191. Consequently, Medicare and its beneficiaries paid approximately \$37 million more for L0631 back orthoses than suppliers paid to acquire them. Beneficiary copayments alone would have almost covered suppliers' L0631 acquisition costs. The description for the L0631 back orthosis code includes not only the orthosis but also fitting and adjustment services. However, for one-third of claims, suppliers did not report providing fitting and adjustment services. For 93 percent of claims, suppliers did not report providing any additional services regarding the L0631 back orthoses other than general instructions.

WHAT WE RECOMMEND

We recommend that CMS use supplier acquisition cost information to lower the fee schedule amount for L0631 back orthoses by including it in the Competitive Bidding Program or by using CMS's inherent reasonableness authority. CMS concurred that Medicare payments for L0631 back orthoses should be adjusted to more closely reflect supplier acquisition costs and the level of service provided when furnishing the devices.

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OBJECTIVES

1. To compare the Medicare payment amount for L0631 back orthoses to supplier acquisition cost.
2. To determine the extent to which suppliers provided services to Medicare beneficiaries who received L0631 back orthoses.

BACKGROUND

The number of Medicare claims and total allowances for L0631 back orthoses rose sharply from 2008 to 2011. During that time, Medicare allowances for L0631 back orthoses more than doubled, increasing from \$36 million in 2008 to more than \$96 million in 2011.¹ Although Medicare pays for 13 different lower-back orthoses codes, in 2011 it paid more for orthoses coded as L0631 than the other 12 lower-back orthoses codes combined.²

Medicare Coverage of Back Orthoses

Back orthoses provide back support, reduce back pain, and facilitate healing of the spine. Medicare covers back orthoses prescribed for one of the following indications:

- to reduce pain by restricting mobility of the trunk,
- to facilitate healing following an injury to the spine or related soft tissue,
- to facilitate healing following a surgical procedure on the spine or related soft tissue, or
- to otherwise support weak spinal muscles and/or a deformed spine.³

To bill Medicare, a supplier must have a written order from a physician indicating that the back orthosis is reasonable and necessary for the beneficiary. Beneficiaries obtain back orthoses from suppliers, which purchase them from manufacturers and wholesalers.

¹ Summary analysis of the Centers for Medicare & Medicaid Services' (CMS) Services Tracking, Analysis, & Reporting System National Database.

² Ibid.

³ *Local Coverage Determination (LCD) for Spinal Orthoses: TLSO and LSO (L11470)*, January 1, 2010. This is the LCD for one of the four claims processors for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The other three claims processors have identical LCDs. LCD L11470 was accessed at http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L11470_2010-01-01_PA_2010-07.pdf on October 5, 2011.

Medicare Payment for Back Orthoses

To obtain payment for covered equipment, suppliers submit claims using procedure codes. The Healthcare Common Procedure Coding System (HCPCS) provides a standardized coding system for describing specific items and services provided. In the case of back orthoses, each HCPCS code defines a type of orthosis but does not specify the individual models covered under each code. Therefore, a single HCPCS code can be used to bill for a number of different manufacturers' products as long as they meet the requirements outlined in the definition of the code.

There are 13 HCPCS codes (L0628 through L0640) for lumbar-sacral (lower-back) orthoses.⁴ Medicare allowed \$166 million for all lumbar-sacral orthoses codes. Medicare allowed \$96 million for code L0631 alone—58 percent of the total 2011 payments for all lumbar-sacral orthoses.⁵ Medicare-allowed amounts include the 80 percent that Medicare pays and the 20 percent the beneficiary pays as a copayment.

The L0631 code is one of seven lumbar-sacral codes for prefabricated back orthoses. The remaining six lumbar-sacral codes are for custom-fabricated back orthoses. According to local coverage policy articles for back orthoses, prefabricated back orthoses are “manufactured in quantity without a specific patient in mind” and custom-fabricated orthoses are “individually made for a specific patient.”⁶

Medicare payment amounts for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) are based on fee schedules. Medicare pays the lower of the supplier charge for the item or the fee schedule amount. Medicare uses a separate fee schedule for each State to account for geographic differences in prices. For prosthetics and orthotics, Medicare uses regional fee schedule amounts, which are the weighted averages of the statewide fee schedule amounts in each CMS region.

⁴ According to the LCD in note 3 above, L0631 is defined as “lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavity pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, includes fitting and adjustment.”

⁵ Summary analysis of CMS' Services Tracking, Analysis, & Reporting System National Database.

⁶ *Local Coverage Article for Spinal Orthoses: TLSO and LSO (A23663)*, July 1, 2010. This is the Policy Article for one of the four DMEPOS claims processors. The other three claims processors have identical Policy Articles. Policy Article A23663 was accessed at http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L11470_2010-01-01_PA_2010-07.pdf on October 5, 2011.

The 2011 fee schedule amounts for L0631 ranged from \$906.34 to \$940.65.⁷

The payment amount for L0631 includes fitting and adjustment services. The local coverage determinations for back orthoses do not define “fitting and adjustment.” They also do not specify that certain types of personnel, such as certified orthotists, should perform fitting and adjustment services. Suppliers are not required to provide any additional services to beneficiaries receiving L0631 back orthoses.

Competitive Bidding for DMEPOS

For some DMEPOS, payment amounts are set through competitive bidding in certain jurisdictions. Under the DMEPOS Competitive Bidding Program, suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in a geographical area. CMS awards contracts to suppliers that offer lower prices and meet the program’s quality and financial standards.⁸ However, back orthoses are not among the DMEPOS items included in competitive bidding.

Inherent Reasonableness Authority

CMS has the authority to adjust Medicare payment amounts that are not inherently reasonable.⁹ The Act requires that payments made under Medicare Part B be “reasonable.”¹⁰ The Act provides that CMS may establish a special reasonable payment limit for a category of service if, after consultation with representatives of affected parties (such as suppliers), it determines that payment amounts are grossly deficient or excessive. CMS staff reported that, since the implementation of fee schedules in 1989, the agency has used its inherent reasonableness authority successfully once, in 1995, to lower the payment amounts for standard home blood glucose monitors.¹¹

METHODOLOGY

Data Sources and Collection

Sample Selection. From CMS’s National Claims History (NCH) file, we extracted all claims for L0631 back orthoses that (1) had dates of service between July 1, 2010, and June 30, 2011; (2) had an allowed charge greater than \$0.00; (3) were from suppliers within the 50 States and the

⁷ The range excludes the fee schedule amounts for Puerto Rico, Virgin Islands, and other U.S. territories.

⁸ Social Security Act (the Act), § 1847(b)(2)(A).

⁹ The Act, §§ 1834(a)(10)(B) and 1842(b)(8) and (9).

¹⁰ Coverage for L0631 back orthoses is provided under Medicare Part B.

¹¹ 60 Fed. Reg. 3405 (Jan. 17, 1995).

District of Columbia; and (4) had a specific National Provider Identifier (NPI) for the supplier. As Table 1 shows, the Medicare allowed amount for all claims in the universe totaled \$83 million.

From this universe of claims we selected a two-stage cluster sample. For the first stage, we randomly selected 350 of the total 3,131 suppliers. These sampled suppliers had between 1 and 3,537 allowed claims. For the second stage, we randomly selected 1 claim from each of the 350 suppliers. We removed two claims filed by two suppliers that were under investigation by the Office of Inspector General's (OIG) Office of Investigations.

Supplier Survey. We used the NPI from each claim to obtain contact information for each supplier from CMS's National Plan & Provider Enumeration System. We sent letters to the suppliers asking them to complete an online survey regarding their L0631 claims and to provide relevant documentation, such as invoices and physician orders. We made a minimum of three written attempts to obtain information from the sampled suppliers. If we received no information after three attempts, we attempted to contact the supplier by telephone and/or email.

For the specific product provided by the supplier, we requested (1) the manufacturer name; (2) the model name; (3) the model number, (4) a description of the item; (5) the acquisition cost (reflective of any discounts, rebates, fees, or charges); and (6) the physician order for the item.

We also requested that each supplier describe the services it provided the beneficiary. We asked suppliers about their fitting and adjustment services, any instructions regarding the use of the orthoses, and a description of any other services provided.

Table 1 shows the number of claims, suppliers, and Medicare-allowed amounts for the population, sample, and survey respondents. We removed six claims for six suppliers that reported they erroneously billed for L0631 back orthoses. In each of those cases, the supplier billed Medicare for an L0631 orthosis but actually provided the beneficiary with some other type.

Twenty-one suppliers did not complete the survey. Of those, four did not complete the survey because their businesses had closed. Four could not be reached because their addresses were incorrect and their letters were returned as undeliverable. Another 13 suppliers never responded after receiving our survey request letters and followup calls.¹²

¹² OIG referred the 21 suppliers that did not respond to the survey to CMS.

Table 1: Population and Sample Size

	Population	Sample	Respondents
Suppliers	3,131	350	321
Claims	90,181	350	321
Allowed Amount	\$82,819,632	\$319,592	\$293,901

Source: OIG analysis of claims extracted from NCH file.

We reviewed 321 claims from the 321 suppliers that responded to the survey. One respondent provided documentation but did not complete the survey. However, on the basis of its documentation, we included that supplier in our analysis.

Data Analysis

For the 321 suppliers who responded to our survey, we compared Medicare’s allowed amount to supplier acquisition costs for L0631 back orthoses and determined the extent to which suppliers provided services associated with them.

Supplier Acquisition Cost. To calculate the supplier acquisition cost for each orthosis, we asked suppliers to provide the invoice purchase prices as well as any discounts or fees associated with the purchases. To calculate acquisition cost, we subtracted any discounts from the invoice purchase price and added any fees. When suppliers provided prices, discounts, or fees that were not supported in their documents, we used the information in the documentation for our calculations. The calculation of acquisition cost does not include a supplier’s indirect costs, such as the cost of performing services or other supplier business expenses.

Discounts received by suppliers included rebates, prompt-pay discounts, volume discounts, and other discounts. Fees paid by suppliers included delivery charges, fuel charges, and sales taxes. When suppliers received orthoses as part of a delivery with other items, we prorated the delivery charge on the basis of the number of items on the shipment documentation provided by the suppliers. In five cases, suppliers did not have documentation indicating the number of other items that were included with shipment of the orthoses. We used the full delivery charges they reported for our calculations.

Differences Between Allowed Amount and Supplier Acquisition Cost. For each claim in the sample, we calculated the difference between the Medicare-allowed amount and the supplier acquisition cost. We then calculated the average dollar amount difference across all claims. We projected this difference to determine the total dollar amount difference

between what Medicare and its beneficiaries paid and what suppliers paid for the orthoses. We also calculated the average percentage difference between the Medicare-allowed amount and the supplier acquisition cost.

We also analyzed beneficiary copayments for L0631 back orthosis claims. From the copayment information included on each claim, we calculated the average beneficiary copayment across all claims. In addition, we totaled beneficiary copayment amounts across all L0631 back orthosis claims.

Models of Common L0631 Orthoses Provided by Suppliers. For each claim, we requested that the supplier report the manufacturer and model of the orthosis provided. We aggregated suppliers' responses to determine which models were most commonly provided.

Services Provided by Supplier. We calculated the percentage of claims that involved fitting and adjustment services provided by suppliers. We also calculated the percentage of claims in which suppliers provided fitting and adjustment services at the beneficiaries' homes, on the suppliers' premises, or at other locations. We calculated the percentage of fitting and adjustment services provided by physicians; certified orthotists; office personnel; or others, such as manufacturer representatives.

We also calculated the percentage of claims in which suppliers provided instructions to beneficiaries and the percentage of claims in which suppliers provided any other services.

Type of Delivery. We determined how suppliers delivered L0631 back orthoses. Each supplier indicated whether the orthosis was provided on the supplier's premises, by personal delivery from the supplier to the beneficiary, through a third-party parcel service, by direct delivery from the manufacturer of the orthosis, or by some other means. We calculated the percentage of claims for which suppliers used each method.

Point Estimates and Confidence Intervals. We developed point estimates and confidence intervals at the 95-percent confidence level for all statistics presented in the findings of this report. This information is provided in Appendix A. While the response rate for suppliers surveyed was 92 percent (321 of 350), the claims associated with these 321 suppliers represented 56 percent of the claims associated with all 350 sampled suppliers. Therefore, the results of our analysis are representative only of 56 percent of the entire population of L0631 claims.

FINDINGS

Medicare payment amounts were more than four times greater than the supplier acquisition costs for L0631 back orthoses

Between July 1, 2010, and June 30, 2011, the average Medicare-allowed amount was 380 percent higher than the average supplier acquisition cost. During that period, the average Medicare-allowed amount for L0631 back orthoses was \$919, which was more than four times greater than the average acquisition cost of \$191. The average difference between the Medicare-allowed amount and supplier acquisition costs was \$728. Medicare allowed between \$400 and \$942 for L0631 back orthoses, while suppliers paid as little as \$0 and as much as \$995 for them.¹³

For almost all claims (99.6 percent), the Medicare-allowed amounts exceeded the suppliers' acquisition costs. Suppliers purchased 75 percent of orthoses for \$234 or less, half for \$168 or less, and 25 percent for \$152 or less.

Medicare and its beneficiaries paid \$37 million more for L0631 back orthoses than suppliers paid to purchase them

Medicare allowed a total of \$83 million for L0631 claims between July 1, 2010, and June 30, 2011.¹⁴ Medicare and its beneficiaries paid \$37 million more for L0631 back orthoses than suppliers paid to acquire them.¹⁵

Beneficiary copayments alone would have almost covered suppliers' L0631 acquisition costs. Beneficiaries are responsible for paying 20 percent of the Medicare-allowed amount for back orthoses. The average beneficiary copayment for L0631 orthoses was \$184, while the average supplier acquisition cost was \$191. Collectively, beneficiaries paid \$9.3 million for L0631 back orthoses that cost suppliers \$9.7 million.

¹³ One supplier reported paying nothing for its L0631 orthosis because the vendor provided it as a sample, free of charge. OIG referred this supplier to CMS.

¹⁴ Total allowances are for the claims that met the parameters outlined in the Methodology section of this report.

¹⁵ As described in the Methodology section, the results of our analysis represent 56 percent, or \$47 million, of the entire population of L0631 claims. The \$37 million is calculated on the basis of this \$47 million.

Discounts and fees did not substantially affect suppliers' acquisition costs for L0631 orthoses

Suppliers received discounts on 22 percent of the orthoses they purchased. The average discount was \$11 (this includes volume discounts, prompt-pay discounts, rebates, and other discounts). Suppliers paid delivery fees or other fees, such as sales tax, on 62 percent of the orthoses they purchased. The average fee was \$7. We factored discounts and fees into the suppliers' acquisition costs.

The majority of claims were for orthoses that suppliers acquired directly from manufacturers

For 67 percent of claims, suppliers purchased L0631 back orthoses directly from manufacturers. Another 31 percent of orthoses were purchased from wholesalers and 2 percent from other sources, such as distributors or retailers. Back orthoses purchased from manufacturers were slightly less expensive than those purchased from wholesalers. On average, suppliers purchasing from manufacturers paid \$180 while those purchasing from wholesalers paid \$212. The few suppliers who acquired orthoses from other sources paid an average of \$256.

Three orthosis models accounted for almost half (48 percent) of all L0631 claims

The Prolign model, manufactured by DeRoyal Industries, Inc., accounted for 28 percent of L0631 claims. The DDS-500 model, manufactured by Disc Disease Solutions, Inc., and the Summit model, manufactured by Aspen Medical Products, Inc., each accounted for 10 percent. Appendix B lists all of the manufacturers and models reported by suppliers and provides point estimates for the percentage of claims associated with each.

Suppliers did not report providing fitting and adjustment services for one-third of claims

Fitting and Adjustment Services. Fitting and adjustment services are included in the payment amount for L0631 back orthoses. For one-third of claims, suppliers did not report providing fitting and adjustment services to beneficiaries. Among the remaining two-thirds of claims, the extent of the reported fitting and adjustment services varied. Some suppliers' documentation indicated that the services entailed taking measurements, such as the beneficiary's hip and waist size. Other suppliers' documentation indicated that they made physical adjustments to back orthoses to fit beneficiaries properly.

For 42 percent of claims involving fitting and adjustment services, suppliers reported that the services were provided not by specialized staff,

but by office personnel. A certified orthotist provided fitting and adjustment services for 9 percent of claims. Another 48 percent of claims involved services performed by physicians or other professionals, such as registered nurses, chiropractors, physical therapists, or DMEPOS fitters. For the remaining 1 percent of claims, fitting and adjustment services were provided by others, such as manufacturing representatives.

The majority of fitting and adjustment services were not provided in beneficiaries' homes. Suppliers reported providing 58 percent of fitting and adjustment services on the suppliers' premises. About a quarter (27 percent) of fitting and adjustment services were provided in beneficiaries' homes. Another 15 percent were provided in other locations, such as a doctor's office.

Additional Services. Although most suppliers (91 percent) provided general instructions on the use of the back orthosis, for the vast majority of claims (93 percent), suppliers did not report providing any other types of services regarding L0631 back orthoses.¹⁶ Additional services that were reported included making followup phone calls and providing information regarding patient rights and responsibilities.

Delivery Services. For many claims, suppliers did not provide personal delivery to beneficiaries. Forty-three percent of claims were from suppliers that provided orthoses to beneficiaries on the suppliers' premises. For 19 percent of claims, suppliers used third parties (e.g., UPS, FedEx) to ship the orthoses to beneficiaries. For 38 percent, suppliers delivered the orthoses to beneficiaries.

¹⁶ General instructions include information such as the proper way to put on and remove the back orthosis as well as its cleaning and care.

CONCLUSION AND RECOMMENDATION

Medicare payment amounts were substantially more than suppliers' acquisition costs for L0631 back orthoses. Consequently, Medicare and its beneficiaries paid approximately \$37 million more for these orthoses than suppliers paid to purchase them. For one-third of claims, suppliers did not provide the fitting and adjustment services included in the payment amounts. For the vast majority of claims (93 percent), suppliers did not provide any additional services related to L0631 back orthoses other than general instructions.

The significant difference between the Medicare allowed-amount and supplier acquisition cost, especially in light of the noncustomized nature of the L0631 back orthosis and the limited services provided to beneficiaries, warrants an examination by CMS of its current payment amount.

We recommend that CMS:

Lower the Fee Schedule Amount for the L0631 Back Orthosis

CMS could take one of the following actions:

- Include the L0631 back orthosis in the DMEPOS Competitive Bidding Program. CMS could award contracts to suppliers that offer more appropriate prices while also meeting the program's quality and financial standards.
- Use its inherent reasonableness authority. The Medicare-allowed amount for L0631 back orthoses exceeded the supplier acquisition cost by an average of \$728. The program and its beneficiaries could have paid millions of dollars less if the Medicare reimbursement amount for L0631 back orthoses more closely resembled the cost to suppliers.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred that Medicare payments for L0631 back orthoses should be adjusted to more closely reflect the suppliers' acquisition costs for the devices and the level of service provided when furnishing them. CMS stated that it has invited comments on a list of HCPCS codes, including code L0631, that were preliminarily classified as meeting the definition of off-the shelf (OTS) orthotics. OTS orthotics, which require minimal self-adjustment and do not require individual customization, are subject to the DMEPOS Competitive Bidding Program. CMS stated that it is carefully considering comments and consulting with experts in the orthotics field as it works toward finalizing Medicare's classification of OTS orthotic codes. It believes that implementing competitive bidding for OTS orthotics would result in new payment amounts for these items in competitive bidding areas. CMS reported that, at this time, it does not want to use its inherent reasonableness authority to adjust the payment amounts as it is unlikely to undertake the required analysis prior to completing the classification of OTS orthotic codes.

The full text of CMS's comments is provided in Appendix C.

APPENDIX A

Table A-1: Point Estimates and Confidence Intervals for L0631 Back Orthoses Findings

Estimate Description	Number of Sample Responses	Point Estimate	95% Confidence Interval
Percentage by which the average Medicare- allowed amount exceeded the average supplier acquisition cost	321	380%	335% to 426%
Average Medicare-allowed amount	321	\$919	\$914 to \$924
Average acquisition cost	321	\$191	\$173 to \$210
Average difference between the Medicare-allowed amount and supplier acquisition cost	321	\$728	\$710 to \$745
Percentage of claims for which the Medicare-allowed amounts exceeded suppliers' acquisition costs	321	99.59%	97.57% to 99.93%
Median acquisition cost	321	\$168	\$147 to \$188
Supplier acquisition cost 75 th percentile	321	\$234	\$209 to \$259
Supplier acquisition cost 25 th percentile	321	\$152	\$138 to \$166
Percentage of claims for which the supplier acquisition costs included discounts	321	22%	9% to 46%
Average amount of discounts received by suppliers	65	\$11	\$2 to \$19
Percentage of claims for which the supplier acquisition costs included fees	321	62%	44% to 78%
Average amount of fees paid by suppliers	199	\$7	\$5 to \$9
Percentage of claims for orthoses acquired from manufacturers	321	67%	52% to 79%
Percentage of claims for orthoses acquired from wholesalers	321	31%	19% to 45%

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Table A-1: Point Estimates and Confidence Intervals for L0631 Back Orthoses Findings (continued)

Estimate Description	Number of Sample Responses	Point Estimate	95% Confidence Interval
Percentage of claims for orthoses acquired from other sources	321	2%	1% to 5%
Average price of orthoses acquired from manufacturers	170	\$180	\$156 to \$204
Average price of orthoses acquired from wholesalers	130	\$212	\$184 to \$240
Average price of orthoses acquired from other sources	21	\$256	\$213 to \$299
Percentage of claims for Prolign L0631 back orthoses	321	28%	13% to 50%
Percentage of claims for Summit L0631 back orthoses	321	10%	5% to 17%
Percentage of claims for DDS-500 L0631 back orthoses	321	10%	3% to 24%
Additional amount that Medicare and its beneficiaries paid compared to suppliers' acquisition costs	321	\$36,811,464	\$25,098,260 to \$48,524,668
Average beneficiary copayment	321	\$184	\$183 to \$186
Total beneficiary copayments	321	\$9,327,080	\$6,446,557 to \$12,207,602
Total supplier acquisition cost	321	\$9,686,441	\$6,830,225 to \$12,542,656
Percentage of suppliers that provided instructions to beneficiaries	321	91%	83% to 96%
Percentage of suppliers that did not report providing fitting and adjustment services	321	33%	18% to 53%
Percentage of fitting and adjustment services provided on suppliers' premises	266	58%	42% to 72%
Percentage of fitting and adjustment services provided in beneficiaries' homes	266	27%	15% to 43%
Percentage of fitting and adjustment services provided in other locations	266	15%	7% to 32%

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Table A-1: Point Estimates and Confidence Intervals for L0631 Back Orthoses Findings (continued)

Estimate Description	Number of Sample Responses	Point Estimate	95% Confidence Interval
Percentage of fitting and adjustment services provided by office personnel	266	42%	27% to 58%
Percentage of fitting and adjustment services involving certified orthotists	266	9%	6% to 14%
Percentage of fitting and adjustment services provided by physicians or other professionals	266	48%	33% to 63%
Percentage of fitting and adjustment services provided by other staff	266	1%	0.37% to 4%
Percentage of suppliers that reported not providing other types of services related to orthoses	321	93%	84% to 97%
Percentage of suppliers that provided orthoses on their premises	321	43%	29% to 58%
Percentage of suppliers that delivered orthoses through third parties, such as FedEx	321	19%	6% to 46%
Percentage of suppliers that provided orthoses by personal delivery	321	38%	25% to 54%

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

APPENDIX B

Table B-1: L0631 Back Orthosis Models Provided to Beneficiaries

The Centers for Medicare & Medicaid Services contracts with a Pricing, Data Analysis, and Coding (PDAC) Contractor to develop product classification lists that provide information on models of back orthoses that would meet the requirements for the L0631 code. Not all of the manufacturers and models provided below were included in the L0631 Product Classification list displayed on the PDAC Contractor's Web site as of September 2012.

Manufacturer	Model	Point Estimate	95% Confidence Interval
DeRoyal Industries, Inc.	ProLign	28%	13% to 50%
Aspen Medical Products, Inc.	Summit	10%	5% to 17%
Disc Disease Solutions, Inc.	DDS-500	10%	3% to 24%
Bell-Horn/Cybertech Medical	Premium Plus	7%	3% to 17%
Spinal Rehab Solutions, Inc.	SR 500	7%	3% to 18%
American Medical Products	Freedom LSO	6%	2% to 20%
Bauerfeind USA, Inc.	Lumbo Plus	4%	0.76% to 20%
Hope Orthopedic	Ninja LSO	3%	0.71% to 14%
Swedo-O/United Pacific Industries Pty. Ltd.	Thermoskin 87273	3%	0.48% to 17%
BSN Medical/FLA Orthopedics, Inc.	Cinch-Loc	3%	2% to 6%
Ossur Americas, Inc.	Miami	3%	1% to 8%
M-Brace	M-Spine 584	2%	0.69% to 8%
XBACK Bracing Services, Inc.	X-Back T105	1%	0.32% to 7%
Orthomerica Products, Inc.	California Mid Profile	1%	0.61% to 3%
Advanced Orthotic Designs	Lace-it x640 LSO	1%	0.18% to 7%
Aspen Medical Products, Inc.	Aspen LSO	0.92%	0.40% to 2%
Restorative Medical, Inc.	VertebrEase TLSO	0.87%	0.13% to 5%
Optec USA, Inc.	Evotec	0.71%	0.12% to 4%
Med Practice Solutions	Flex LSO	0.71%	0.21% to 2%
ActiveCare Medical/Drive Medical	VerteWrap LSO	0.62%	0.10% to 4%
Aspen Medical Products, Inc.	Aspen LSO LoPro	0.48%	0.09% to 3%
XBACK Bracing Services, Inc.	X-Back-II	0.46%	0.07% to 3%
Breg, Inc.	BOA	0.42%	0.07% to 3%
DeRoyal Industries, Inc.	ProLign EXT	0.42%	0.09% to 2%
XBACK Bracing Services, Inc.	X-Back T102	0.42%	0.14% to 1%
Bledsoe Brace Systems	Volare	0.32%	0.05% to 2%
Restorative Care of America, Inc.	450 LSO	0.28%	0.09% to 0.85%
Orthomerica Products, Inc.	California Chairback	0.23%	0.06% to 0.91%
Hope Orthopedic	Ortholux Lite	0.23%	0.06% to 0.86%
Swede-O, Inc.	Rigid Lumbar Support	0.21%	0.04% to 1%

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**Table B-1: L0631 Back Orthosis Models Provided to Beneficiaries
(continued)**

Manufacturer	Model	Point Estimate	95% Confidence Interval
Advanced Orthopaedics	Spinal Web 31	0.21%	0.04% to 1%
MIH International	ActivDay 501 LSO	0.19%	0.04% to 0.93%
Medical Specialties, Inc.	Archimed Spinal Brace	0.18%	0.03% to 1%
Orthomerica Products, Inc.	California Soft Spinal System LSO with PSR	0.16%	0.04% to 0.62%
Hope Orthopedic	Ortholux LSO	0.14%	0.06% to 0.34%
Optec USA, Inc.	Stealth	0.14%	0.04% to 0.48%
BSN Medical/FLA Orthopedics, Inc.	System-Loc	0.14%	0.02% to 0.92%
DeRoyal Industries, Inc.	Ultralign	0.11%	0.03% to 0.35%
Hope Orthopedic	Vertalux	0.11%	0.02% to 0.69%
Orthomerica Products, Inc.	California Low Profile	0.07%	0.02% to 0.23%
Aspen Medical Products, Inc.	Contour	0.07%	0.01% to 0.46%
Medi USA, LP	Lumbamed Multi Stage Lumbar Support	0.07%	0.01% to 0.46%
Hope Orthopedic	Ninja Pro	0.05%	0.01% to 0.35%
Freeman Manufacturing Co.	C.A.S.H. Orthosis	0.04%	0.01% to 0.23%
Orthomerica Products, Inc.	California CPO Chairback Mid Profile	0.04%	0.01% to 0.23%
Surgical Appliance Industries, Inc.	Lumbotek 2 Lumbosacral Support	0.04%	0.01% to 0.23%
M-Brace	M-Spine 574	0.04%	0.01% to 0.14%
Cybertech Medical	Original and Chairback	0.04%	0.01% to 0.23%
Aspen Medical Products, Inc.	Quickdraw	0.04%	0.01% to 0.14%
Professional Products, Inc.	Rachis	0.04%	0.01% to 0.23%
Swede-O/United Pacific Industries Pty. Ltd.	Thermoskin 85273	0.04%	0.01% to 0.23%
XBACK Bracing Services, Inc.	X-Back T108	0.04%	0.01% to 0.23%
Cropper Medical, Inc./Bio Skin	Black Jack	0.02%	0.003% to 0.12%
Orthomerica Products, Inc.	California Ventura	0.02%	0.003% to 0.12%
Restorative Care of America, Inc.	Control Fit TLSO	0.02%	0.003% to 0.12%
Spinal Technology, Inc.	Custom LSO Lined Single Opening	0.02%	0.003% to 0.12%
US Orthotics	Fullback XPA-10	0.02%	0.003% to 0.12%
Surgical Appliance Industries, Inc.	Knight	0.02%	0.003% to 0.12%
Kydex	Kydex Chairback Brace	0.02%	0.003% to 0.12%
Hely & Weber	Low Profile Solly	0.02%	0.003% to 0.12%
Ottobock	Lumbo Tristep	0.02%	0.003% to 0.12%
Aspen Medical Products, Inc.	Multiple piece system	0.02%	0.003% to 0.12%
Oasis Orthopedics	Oasis TLSO	0.02%	0.003% to 0.12%
NeuMed, Inc.	Orthofect LSO Brace	0.02%	0.003% to 0.12%
Premier Orthopedic Supply, Inc.	Premier LSO	0.02%	0.003% to 0.12%

continued on next page

**Table B-1: L0631 Back Orthosis Models Provided to Beneficiaries
(continued)**

Manufacturer	Model	Point Estimate	95% Confidence Interval
ActiveCare Medical	VerteWrap Low Profile LSO	0.02%	0.003% to 0.12%
XBACK Bracing Services, Inc.	X-Back T100	0.02%	0.003% to 0.12%
Total		99% ¹	

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

¹ The table does not include two back orthoses that two suppliers fabricated.

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 25 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner */S/*
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Supplier Acquisition Costs for L0631 Back Orthoses (OEI-03-11-00600)

The Centers for Medicare & Medicaid Services (CMS) would like to thank you for the opportunity to review and comment on the OIG draft report entitled, "Medicare Supplier Acquisition Costs for L0631 Back Orthoses." The draft report compares suppliers' acquisition costs for back orthoses coded under L0631 with Medicare's 2011 fee schedule amounts. Also detailed within the report is the nature and frequency of services performed by suppliers in relation to L0631 back orthoses.

The OIG draft report provides valuable insight for CMS on suppliers' costs for L0631 back orthoses. Notably, the report reveals that Medicare and beneficiaries paid suppliers an average of \$728 beyond the supplier's acquisition cost for an L0631 back orthosis. This was coupled with a finding that for one third of the claims, suppliers did not provide any fitting and adjustment services. OIG recommendations and CMS's response to those recommendations are discussed below.

OIG Recommendation

The OIG recommends that CMS lower the Fee Schedule Amount for the L0631 Back Orthosis. CMS could take one of the following actions:

- Include the L0631 back orthosis in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. CMS could award contracts to suppliers who offer more appropriate prices while also meeting the program's quality and financial standards.
- Use its inherent reasonableness authority. The Medicare allowed amount for L0631 back orthoses exceeded the supplier acquisition cost by an average of \$728. The program and its beneficiaries could have paid millions of dollars less if the Medicare reimbursement amount for L0631 back orthoses more closely resembled the cost to suppliers.

CMS Response:

The CMS agrees that Medicare payments for back orthoses described by Healthcare Common Procedure Coding System (HCPCS) code L0631 should be adjusted to more closely reflect the supplier's acquisition costs for the device and the level of service provided when furnishing the device. Off-the-shelf (OTS) orthotics are items that are subject to the DMEPOS Competitive Bidding Program and are defined in the Social Security Act to be orthotics which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. We have invited comments on a list of orthotic HCPCS codes, including code L0631 that were preliminarily classified as meeting the OTS definition. CMS is carefully considering the comments and consulting with a variety of individuals, including experts in the orthotic field, as we work toward finalizing Medicare's classification of OTS orthotic codes. Implementing competitive bidding for OTS orthotics would result in new payment amounts for these items in competitive bidding areas.

At this time we do not concur with using the inherent reasonableness authority to adjust the payment amounts as CMS is unlikely to undertake such an analysis prior to completing the classification of OTS orthotic codes.

The CMS would like to thank OIG for their efforts and insight on this important Medicare issue. The report provides valuable information that will assist the Agency in its efforts to ensure appropriate Medicare payment for orthotics. We look forward to working with OIG further on this and other critical issues.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General.

Tanaz Dutia served as the team leader for this study. Other Office of Evaluation and Inspections staff from the Philadelphia regional office who conducted the study include Russell Tisinger and Nancy J. Molyneaux. Central office staff who provided support include Meghan Kearns, Debra Roush, and Tasha Trusty.

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