Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Medicare Payments for Orthotics

Inappropriate Payments

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EXECUTIVE SUMMARY

PURPOSE

To determine the extent of inappropriate Medicare payments for orthotics.

BACKGROUND

This study, a follow-up to a 1997 Office of Inspector General report entitled "Medicare Orthotics" (02-95-00380), was conducted to determine what changes, if any, have occurred with Medicare orthotics. We have also prepared a companion report entitled "Medicare Reimbursement for Orthotics - Carrier Perspectives" (02-99-00121) which examines orthotic policies from the four durable medical equipment regional carriers (DMERCs) and obtains their perspectives on Medicare reimbursement for these devices.

Orthotics are rigid devices, often called braces, which are applied to the outside of the body as a means of support. They are categorized into one of three groups of devices: custom fitted, which require alterations to a prefabricated product; custom fabricated, which are made for a specific patient from his/ her individual measurements; and molded to patient model, which are created from a cast of the patient's body part. Add ons, such as straps and linings, are billed separately. Suppliers of orthotics include certified orthotists, medical equipment companies, and physicians' offices.

Using a stratified random sample of 500 Medicare beneficiaries who had one or more orthotic claims in 1998, we combined three methods for this inspection. They include a beneficiary medical record review, a coding review, and a supplier feedback survey.

FINDINGS

Inappropriate Medicare reimbursement for orthotics continues at significant levels

Thirty percent of beneficiaries have one or more miscoded orthotic device. The miscoded orthotics represent $33,071,800 in excessive Medicare payments when projected to the total Medicare population. Three reasons account for nearly all of this miscoding: the device does not meet the specifications of the code billed; the device is not custom fabricated or molded, as indicated by the code billed; or the part billed is already included in the base code for a larger device.

Seven percent of beneficiaries have one or more medically unnecessary orthotic device. The medically unnecessary orthotics represent $9,935,500 in excessive Medicare payments when projected to the total Medicare population. Most of these beneficiaries lack a medical condition or diagnosis that warrants the prescription of an orthotic device; others could have used a less complex device to obtain the same medical benefit or are inappropriately using a device for preventive or palliative purposes. Another 16 percent of beneficiaries have orthotics that are medically questionable. The medically questionable orthotics represent $1,165,200 in Medicare payments when projected to the total Medicare population.

In addition to the miscoded and medically unnecessary and questionable cases already discussed, other cases appear suspect. Of the 1404 prescribed devices in our sample, 20 percent fall into one of the following 3 categories: we were unable to locate the prescribing physician, the physician reported no record of a patient, or the physician claimed never having ordered the device. These suspect cases represent approximately $28,145,200 in Medicare payments when projected to the total Medicare population.

Lastly, inadequate medical and supplier documentation, as well as limited physician involvement in patient's use of orthotics, also raise questions about the appropriateness of Medicare orthotic payments.

Qualifications of orthotic suppliers vary, with non-certified suppliers in our sample the most likely to provide inappropriate devices

The orthotic suppliers in our sample include a broad range of different provider groups and most commonly include individual certified orthotists and durable medical equipment companies. Our supplier survey reveals that 68 percent of the suppliers in our sample employ and/or contract with certified orthotists and 32 percent do neither. While there are fewer non-certified suppliers than certified suppliers in our sample, non-certified suppliers are more likely than certified suppliers to provide inappropriate devices. Forty-six percent of these suppliers provide inappropriate orthotics, compared to 16 percent of certified suppliers. Miscoding is the main reason devices they supply are inappropriate.

RECOMMENDATIONS

The findings of this report, as well those from the recently released OIG report "Medicare Payments for Orthotic Body Jackets," reveal that Medicare is inappropriately paying for some orthotic devices. Both studies identify miscoding as problematic, particularly for devices that are individually fitted to the patient's measurements. Furthermore, this report shows non-certified suppliers are the most likely to provide inappropriate devices.

We therefore recommend that HCFA take action to improve Medicare billing for orthotic devices.

The HCFA may want to consider the following options:

- *Require suppliers to maintain a description of how custom fabricated and molded devices are made.* The OIG report on orthotic body jackets referenced above recommends that suppliers include detailed information on the products they provide on their claims. The HCFA responded that this would be burdensome to providers and carriers. To avoid such a burden, we suggest that a description need not be detailed and can be kept on file with the supplier. It could include basic information such as whether or not a device was individually fitted to a patient's specific measurements. Such descriptions have already been developed by the SADMERC and are required when suppliers seek clarification on appropriate coding. The SADMERC descriptions could be used as models for suppliers to use when billing for certain orthotic devices.

- *Develop product classification lists for all major groups of orthotic devices*. In its report on orthotic body jackets, the OIG recommended a revision of coding guidelines. In its response, the HCFA stated that it would develop a product classification list for the body jacket code L0430. We believe such lists would also be useful for all orthotic groups. Given the complexity and rapid technological changes in the orthotics industry, understanding the appropriate coding for these devices can be confusing. Product classification lists would help to clarify the appropriate codes for different types of devices. The carriers are already discussing ways in which coding for orthotics can be clarified and we encourage their efforts.

- *Educate the supplier community*. We believe increased education of the supplier community will enhance their understanding of coding requirements and procedures.

- *Work with the DMERCs to strengthen the billing process for orthotics.* In our companion report on carrier perspectives on orthotics, we discuss several carrier practices and suggestions for improving the way in which orthotics are paid. These include developing additional screens and edits, requiring suppliers to submit a patient diagnosis as part of their claim, and establishing more specific guidelines for "miscellaneous" codes.

We also recommend that HCFA require standards for suppliers of custom molded and custom fabricated orthotic devices. Suppliers of these devices must be skilled in fitting and crafting an orthosis to the individual measurements of the patient. We believe that establishing standards would help to ensure that suppliers providing custom molded

and fabricated devices have such skills and that the devices they supply are appropriate. The HCFA may want to consider establishing their own standards for orthotic suppliers or using already established industry certification.

We believe that implementing these recommendations would eliminate as much as $43,007,300 annually in inappropriate Medicare orthotic payments.

Comments

We received comments on the draft report from the Health Care Financing Administration. The HCFA generally concurs with our recommendations. In response to our recommendation that standards be required for suppliers of custom molded and fabricated devices, HCFA states that it is currently working on a proposed rule that will set general provider standards but not specific standards for custom orthotic suppliers. Given the specialized training and skills necessary for fitting and creating custom molded and fabricated devices, we continue to believe in the importance of additional standards for suppliers providing custom devices. The full comments are presented in Appendix D.

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INTRODUCTION

PURPOSE

To determine the extent of inappropriate Medicare payments for orthotics.

BACKGROUND

This study, a follow-up to a 1997 Office of Inspector General report entitled "Medicare Orthotics" (02-95-00380), was conducted to determine what changes, if any, have occurred with Medicare orthotics. In that report, we found that at least 19 percent of orthotics provided are medically unnecessary and that durable medical equipment companies more likely than orthotists to supply the questionable orthotics. We have also prepared a companion report entitled "Medicare Reimbursement for Orthotics - Carrier Perspectives" (02-99-00121) which examines orthotic policies from the four durable medical equipment regional carriers (DMERCs) and obtains their perspectives on Medicare reimbursement for these devices.

Additionally, in September, 1999, the OIG released another follow-up report entitled "Medicare Payments for Orthotic Body Jackets" (04-97-00390). That study reported that while Medicare payments for orthotic body jacket code L0430 had decreased, 42 percent of claims for these devices were upcoded. This upcoding was attributed in part to a lack of coding uniformity and standardization.

Orthotics

Orthotics are rigid devices, often called braces, which are applied to the outside of the body as a means of support. An orthotic device differs from a prosthetic in that, rather than replacing a body part, it supports and/ or rehabilitates existing body parts. Orthotic devices are usually customized for an individual's use and are not appropriate for anyone else. They have evolved in recent years to also include off the shelf devices that can serve functions similar to custom fitted components with little or no alteration necessary. New computer programs are also available which can design orthotic devices based on the patient's individual measurements. Examples of orthotics include spinal body jackets and knee braces.

Individuals requiring orthotics range from the severely disabled, such as paraplegics or quadriplegics, to those who require an ankle brace for better gait or are recovering from a temporary back injury. An individual may need to wear the orthotic continuously for the

duration of his or her lifetime, every day until the condition improves, or for some other time frame as prescribed by a physician.

There are several different ways in which an orthotic may be supplied. Typically, a physician prescribes the orthotic and refers the patient to an orthotist or an orthotic supplier. Orthotic devices may also be supplied by a clinic, hospital, or nursing home. Some orthosis prescriptions are very specific, while others are more general. The supplier uses these prescriptions, as well as their own examination of the patient, to determine the device needed. If a device needs to be made, the patient is likely to return to the supplier to have the device fitted. Ideally, the supplier also instructs the patient on how to put on, take off, and maintain the device, and provides follow-up care, although this is not required for payment.

Medicare Orthotics: Coverage and Payments

Orthotic devices are primarily covered under Medicare Part B. As with all Medicare Part B services, covered orthotics must be reasonable and necessary for the diagnosis or treatment of an illness or injury. In order to meet Health Care Financing Administration (HCFA) coverage requirements, an orthotic must be a rigid or semi-rigid device used either to support a weak or deformed member or to restrict or eliminate motion in a diseased or injured part of the body. Orthotic claims must have a prescription and/ or a certificate of medical necessity signed by a physician.

Orthotic devices are classified into 1 of 465 different codes (L0100 through L4380) in the Common Procedure Coding system HCFA uses for billing. These L-Code listings give a brief description of the device. These listings also define the device as one of three types:

- *Custom fitted,* which require substantial adjustments to a prefabricated item by a specially trained professional to meet the needs and/or unique shape of an individual patient;

- *Custom fabricated,* which are made for a specific patient from his/her individualized measurements and/ or pattern; or

- *Molded to patient model,* whereby a cast is made of the specified body part and is used to create an orthotic device.

Some orthotics may also have additional components which are billed separately. For example, an ankle-foot orthosis may require special strap, joints, or linings that have their own codes and are therefore billed in addition to the basic device.

Durable Medical Equipment Regional Carriers

Orthotic claims are processed and paid for by one of four regional carriers called DMERCs (Durable Medical Equipment Regional Carriers). In October 1993, HCFA began processing all Medicare Part B claims for medical equipment, supplies, orthotics, and prosthetics through these carriers. Their establishment was intended to help eliminate the inconsistency of coverage and reimbursement for medical equipment that had been problematic in the past. The DMERCs are divided into regions A, B, C, and D and cover the entire country. The DMERCs ensure that coverage requirements are met before approving payment and provide educational services to suppliers.

Orthotic Suppliers

Any supplier with a HCFA provider number can provide and bill for orthotics, and no verification is done to specifically address their ability to provide orthotics. Suppliers of orthotic devices include orthotists, medical equipment companies, pharmacies, and doctors' offices. Some general medical equipment suppliers may have an orthotist on staff. Suppliers may manufacture the devices in their own workshops or obtain them from other companies.

Of all these supplier types, only orthotists have professional certification to provide specialist services. An orthotist provides care to patients with disabling conditions of the musculoskeletal structure of the body. At the request of, and in conjunction with physicians, the orthotist assists in formulating prescriptions for orthoses and examines and evaluates the patients' orthotic needs in relation to their functional loss. More specifically, the orthotist:

formulates the device's design and selects materials and components;
makes all necessary casts, measurements, model modifications, and layouts;
performs fittings, including static and dynamic alignments;
evaluates the orthosis on the patient;
instructs the patient in its use; and
maintains patient records.

Two organizations offer orthotist certification: the American Board for Certification in Orthotics and Prosthetics, Inc., (ABC), and the Board of Certification (BOC). The ABC sets standards of competency and grants a Certified Orthotist (CO) credential. To qualify for ABC certification on orthotics, an individual must have a college degree, have completed a postgraduate orthotist certificate program from an accredited institution, and have at least 1 year of patient management experience. The candidate must also pass two written exams and a 3-day clinical exam that tests the ability to design, fabricate, and fit a variety of orthoses. Certified practitioners must meet continuing education requirements

every 5 years to renew their credentials. Currently, there are approximately 3,000 ABC certified orthotists in the United States.

The BOC also certifies orthotists and there are currently more than 900 BOC certified orthotists. In order to sit for the BOC certification exam, which includes written and practical components, the applicant is required to have one or more of the following: a bachelor's degree with a major in orthotics or prosthetics; an associate degree in a related field, or; one or more years of orthotics/ prosthetics education, training and/ or supervised work experience, including intensive study. All BOC orthotists must document a minimum of 2 years (3,900 hours) experience providing direct patient services.

METHODOLOGY

We combined three methods for this inspection: a medical record review, a coding review, and a supplier feedback survey.

Sample

We selected a stratified random sample of 500 Medicare beneficiaries from the 1 percent National Claims History file who had one or more orthotic claim paid in 1998. We excluded beneficiaries from skilled nursing facilities as well as beneficiaries with claims totaling less than 50 dollars. We then stratified the remaining beneficiaries into three groups of high, medium, and low utilization based on the dollar amount of their collective payments. The low stratum consisted of beneficiaries with orthotic claims totaling less than 500 dollars, the medium stratum consisted of those with between 500 and 1,000 dollars of orthotic claims, and the high stratum comprised beneficiaries whose total claims were greater than 1,000 dollars.

Of the 500 beneficiaries in our sample, 63 percent had 1 orthotic device billed during 1998, 29 percent had 2 devices, and the remaining 31 percent had 3 or more devices billed during that time period. The 500 beneficiaries had a total of 1,404 devices.

Medical Record Review

The 500 beneficiaries in our sample had 521 prescribing physicians. We requested medical records from all 521 physicians from April to June 1999, and received a response from 388, for a response rate of 74 percent; see Appendix C for a non-respondent analysis. We were unable to locate 43 physicians.

Of the 388 responding physicians:

- 304 provided a medical record;
- 43 indicated that they had no record of the patient;
- 16 indicated they had not prescribed the device; and
- 26 responded with only a letter discussing the reason why they ordered an orthotic for their patient.

Once we obtained the medical records, we used a medical review contractor to review the records to determine if the orthotic(s) the beneficiary had a claim paid for was medically necessary. Using a screening instrument based on DMERC medical guidelines and input from one of the DMERC medical directors, an occupational therapist screened records and passed any records which failed the initial screening to a physician who then made a final determination of medical necessity.

Coding Review

The 500 beneficiaries in our sample had 547 orthotic suppliers. We requested documentation on the device(s) provided from all 547 suppliers from April to June 1999. We received information from 412 suppliers, for a response rate of 75 percent; see Appendix C for a non-respondent analysis. Most of these suppliers provided some combination of a brochure or pamphlet, invoice, photocopy from the AOPA orthotic manual, or a claim form.

Once we obtained information from the suppliers, the HCPCS coordinator at the Statistical Analysis DMERC reviewed the documentation to determine if the orthotic(s) the beneficiary had a claim paid for was appropriately coded. The HCPCS unit at this carrier is responsible for resolving coding issues and provides guidance to providers on the appropriate codes to use. Using a structured review sheet to evaluate the materials sent to us by suppliers, the reviewer made a final determination of appropriate coding.

Supplier Survey

We also conducted a mail survey of all of the suppliers in our sample. Along with documentation for the devices they supplied, we asked them to fill out and return a short survey about their staff. We specifically asked if they employ or contract with certified orthotists, who molds and fits devices, or who supervises the crafting of orthotics. Of the 547 suppliers in our sample, 412 returned our feedback survey, for a response rate of 75 percent. While we are unable to project to the universe of all orthotic suppliers, we report the findings of this survey within the context of suppliers in our sample.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

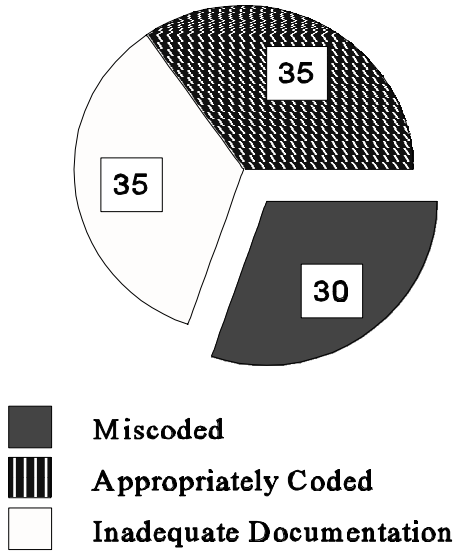
FINDINGS

Inappropriate Medicare reimbursement for orthotics continues at significant levels

One-third of Medicare beneficiaries have miscoded orthotics

Based on the coding review, 30 percent of beneficiaries have miscoded orthotics, as illustrated in Chart 1 below. This represents 22 percent of the 1404 devices billed for our sample beneficiaries.

Chart 1
Medicare Beneficiaries Using Orthotics: Coding Review



The miscoded orthotics used by these beneficiaries represent $33,071,800 in excessive Medicare payments when projected to the total Medicare population. This is a conservative estimate, however, since we assumed that all the beneficiaries for whom we had inadequate information had appropriately coded orthotics.

Three reasons account for nearly all of this miscoding: the device does not meet the specifications of the code billed; the device is not custom fabricated or molded, as indicated by the code billed; or the part billed is already included in the base code for a larger device. Examples of typical miscoding include:

a less expensive off-the-shelf device without individualized fitting that was coded as an orthosis that should have been molded to a plaster model of the patient;

a flexible device that was coded as an orthosis that should have provided rigid control;

a device that was worn without a shoe but was coded as an orthosis that was designed to be worn with a supportive shoe; and

devices that are not orthotics at all but some other item, such as a girdle or athletic sock.

All orthotics must meet general Medicare guidelines in order to be covered. However, several groups of devices lack any additional coverage guidelines specific to their use. These include upper limb and hip devices, most of which have no requirement that they be individually fitted to the patient. A majority of the miscoded devices we reviewed (59 percent) do not have additional coverage guidelines specific to their use.

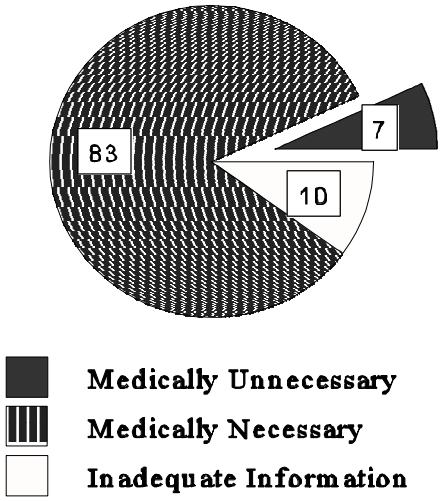
Many beneficiaries with miscoded orthotics (43 percent) have more than one device that is problematic. Of these, many have 3 or more miscoded devices. In some instances, it is the combination of devices used that is not appropriate. For example, a beneficiary may not have needed a particular add-on to their base orthotic or may have had more than one add-on device.

Seven percent of beneficiaries have medically unnecessary orthotics

Based on the medical necessity review, 7 percent of beneficiaries have one or more orthotic devices that is medically unnecessary, as illustrated in Chart 2 on the following page. This represents 7 percent of the 1404 devices billed for our sample beneficiaries.

Chart 2

Medicare Beneficiaries Using Orthotics: Medical Necessity Review



The medically unnecessary orthotics used by these beneficiaries represent $9,935,500 in excessive Medicare payments when projected to the total Medicare population. This is a conservative estimate, however, since we assumed that all the beneficiaries for whom we had inadequate information had medically necessary devices.

Most of the beneficiaries with medically unnecessary devices lack a medical condition or diagnosis that warrants the prescription of an orthotic device. Some beneficiaries could have used a less complex device to obtain the same medical benefit. Other reasons for the lack of medical necessity include the use of an orthosis for preventive or palliative purposes and a lack of evidence that the device is rehabilitative. Specific examples of beneficiaries using medically unnecessary devices include:

a wheelchair-dependent patient who received devices to assist with ambulation;

a patient who was prescribed an orthotic device for a foot condition that developed only after the device was used; and

a patient who had both a shoulder brace and an ankle-foot orthotic but whose medical records only indicate a need for the latter.

About half of beneficiaries with medically unnecessary orthotics have more than one problematic device. For example, a beneficiary may have obtained several devices over a short time frame when not all were required. In one case, one beneficiary received six of the same ankle-foot device within 1 year.

An additional 16 percent of beneficiaries have orthotics that are medically questionable

An additional 16 percent of beneficiaries have medically questionable orthotics. The medically questionable orthotics used by these beneficiaries represent $1,165,200 in Medicare payments when projected to the total Medicare population. In these cases, while there was often insufficient information to make a final determination on medical necessity, the physician reviewer noted devices that are suspect. In many of these cases, our physician reviewer noted a questionable medical need for the device being used and a lack of documentation of the specific medical condition for which a device was prescribed. In other cases, there was no match between the device provided and the device prescribed or the claim date preceded the date of the physician prescription. Another physician ordered the same exact devices for all of his patients, regardless of their medical condition. The physician reviewer also questioned the need for certain add-on devices and multiple billings for the same device. In several cases, beneficiaries were provided with non-corrosive finishes to braces that were made of stainless steel.

Other cases are highly suspect

In addition to the miscoded and medically unnecessary and questionable cases already discussed, other cases appear suspect. Of the 1404 prescribed devices, 20 percent fall into one of the following 3 categories: we were unable to locate the prescribing physician, the physician reported no record of a patient, or the physician claimed never having ordered the device. These suspect cases represent approximately $28,145,200 in Medicare payments when projected to the total Medicare population.

Inadequate documentation and limited physician involvement also raise questions about the appropriateness of Medicare orthotic payments

Inadequate documentation. One concern noted in our reviews is the lack of adequate documentation to support beneficiaries' appropriate use of orthotics.

Thirty-five percent of beneficiaries had suppliers who sent insufficient information to determine coding accuracy. Most of these were custom fabricated and molded devices for which the supplier sent only a picture of the device from an industry manual. Without an accompanying description of how the device was molded and fitted to the patient's individual measurements, our coding reviewer was reluctant to make a final decision on coding accuracy.

Ten percent of beneficiaries had physicians who had inadequate documentation to determine medical necessity. Of the cases passed to a physician for review, 10 percent had inadequate medical information for our physician reviewer to make a determination on medical need.

Limited physician involvement. Our medical record review also revealed a lack of physician involvement in beneficiaries' use of orthotics. Although physicians must sign the order for their patient's device, there is not always an indication of their follow-up or other involvement. More specifically, only 63 percent of devices were selected by patient's physicians, and just 10 percent of devices are being used with a plan of care. Also, physician's notes are not consistently specific as to their patient's need for an orthosis and do not always address how the device should be used.

Furthermore, beneficiaries using orthotics appear to not always be receiving adequate care. Only one-third of devices are being used with follow-up care to assure they are working as intended and are benefitting patients medically. Nearly one half of the devices (47 percent) are not being used with physical therapy and more than half (64 percent) are not being used with occupational therapy, both of which could facilitate patient's rehabilitation .

The qualifications of orthotic suppliers vary, with non-certified suppliers in our sample the most likely to provide inappropriate devices

Different groups supply orthotics

The orthotic suppliers in our sample include a broad range of different provider groups. They most commonly include individual certified orthotists and prosthetists, as well as large durable medical equipment companies, some of whom report having certified orthotists on staff. Podiatrists, orthopedic surgeons, and general practice physicians are also providing beneficiaries with orthotic devices. Less typically, the suppliers in our sample include hospitals, radiologists, dermatologists, neurosurgeons, cardiologists, and anesthesiologists.

Our supplier survey reveals that the qualifications of orthotic suppliers in our sample also differ. Sixty-eight percent are certified; of these, some employ certified orthotists, some contract with certified orthotists, and others do both. These differences in supplier qualifications are illustrated in Table 1 on the following page.

Table 1
Orthotic Suppliers' Staff Qualifications

Staff Qualification	% of Suppliers*
Certified Orthotist on Staff	52
Contract with Certified Orthotist	9
Both	7
Neither	32

*25% of suppliers did not return survey Source: Supplier Feedback Survey

Some orthotic suppliers also use technicians to mold and fit orthotic devices. According to our survey, when specifically asked who molds and fits orthotics, 57 percent of respondents said non-certified staff. However, most have a certified orthotist supervising the molding and fitting.

Nearly half of non-certified suppliers provide inappropriate devices

As shown in Table 1 above, we classify a supplier as non-certified if it has no certified orthotist on staff or does not contract with certified orthotists. While there are fewer non-certified suppliers than certified suppliers in our sample, non-certified suppliers are more likely than certified suppliers to provide inappropriate devices. Nearly half of these suppliers (46 percent) provide inappropriate orthotics, compared to 16 percent of certified suppliers. Miscoding appears to be the major problem with the devices provided by non-certified suppliers. Most of the inappropriate devices they provide are inappropriate because they are not accurately coded. Furthermore, some suppliers provided insufficient documentation to make a determination on coding accuracy. Certified suppliers are the most likely to provide such insufficient documentation.

RECOMMENDATIONS

The findings of this report, as well those from the recently released OIG report "Medicare Payments for Orthotic Body Jackets," reveal that Medicare is inappropriately paying for some orthotic devices. Both studies identify miscoding as problematic, particularly for devices that are individually fitted to the patient's measurements. Furthermore, this report shows that non-certified suppliers are the most likely to provide inappropriate devices.

We therefore recommend that HCFA take action to improve Medicare billing for orthotic devices.

The HCFA may want to consider the following options:

- *Require suppliers to maintain a description of how custom fabricated and molded devices are made.* The OIG report on orthotic body jackets referenced above recommends that suppliers include detailed information on the products they provide on their claims. The HCFA responded that this would be burdensome to providers and carriers. To avoid such a burden, we suggest that a description need not be detailed and can be kept on file with the supplier. It could include basic information such as whether or not a device was individually fitted to a patient's specific measurements. Such descriptions have already been developed by the SADMERC and are required when suppliers seek clarification on appropriate coding. The SADMERC descriptions could be used as models for suppliers to use when billing for certain orthotic devices.

- *Develop product classification lists for all major groups of orthotic devices*. In its report on orthotic body jackets, the OIG recommended a revision of coding guidelines. In its response, the HCFA stated that it would develop a product classification list for the body jacket code L0430. We believe such lists would also be useful for all orthotic groups. Given the complexity and rapid technological changes in the orthotics industry, understanding the appropriate coding for these devices can be confusing. Product classification lists would help to clarify the appropriate codes for different types of devices. The carriers are already discussing ways in which coding for orthotics can be clarified and we encourage their efforts.

- *Educate the supplier community.* We believe increased education of the supplier community will enhance their understanding of coding requirements and procedures.

- *Work with the DMERCs to strengthen the billing process for orthotics.* In our companion report on carrier perspectives on orthotics, we discuss several carrier practices and suggestions for improving the way in which orthotics are paid. These include developing additional screens and edits, requiring suppliers to submit a patient diagnosis as part of their claim, and establishing more specific guidelines for "miscellaneous" codes.

We also recommend that HCFA require standards for suppliers of custom molded and custom fabricated orthotic devices. Suppliers of these devices must be skilled in fitting and crafting an orthosis to the individual measurements of the patient. We believe that establishing standards would help to ensure that suppliers providing custom molded and fabricated devices have such skills and that the devices they supply are appropriate. The HCFA may want to consider establishing their own standards for orthotic suppliers or using already established industry certification.

We believe that implementing these recommendations would eliminate as much as $43,007,300 annually in inappropriate Medicare orthotic payments.

Comments

We received comments on the draft report from the Health Care Financing Administration. The HCFA generally concurs with our recommendations. In response to our recommendation that standards be required for suppliers of custom molded and fabricated devices, HCFA states that it is currently working on a proposed rule that will set general provider standards but not specific standards for custom orthotic suppliers. Given the specialized training and skills necessary for fitting and creating custom molded and fabricated devices, we continue to believe in the importance of additional standards for suppliers providing custom devices. The full comments are presented in Appendix D.

APPENDIX A

CONFIDENCE INTERVALS FOR KEY ESTIMATES

We calculated confidence intervals for five key estimates. The point estimate and 95% confidence interval are given for each of the following:

KEY ESTIMATE	POINT ESTIMATE	CONFIDENCE INTERVAL
Beneficiaries with miscoded device(s)	30%	+/- 4%
Beneficiaries with medically unnecessary device(s)	7%	+/- 4%
Beneficiaries with medically questionable device(s)	16%	+/- 6%
Suspect cases (devices that physician did not prescribe, physician had no record of patient for, or for which we were unable to locate the physician)	20%	+/- 3%
Certified suppliers in sample	68%	+/- 7%

APPENDIX B

CONFIDENCE INTERVALS FOR DOLLAR PROJECTIONS

We calculated confidence intervals for our dollar projections. The projected total and 95% confidence interval are given for each of the following:

CATEGORY	PROJECTED TOTAL	CONFIDENCE INTERVAL
Miscoded devices	$33,071,800	+/- $6,341,00
Medically unnecessary devices	$ 9,935,507	+/- $4,440,683
Medically questionable devices	$ 1,165,224	+/- $1,017,577
Suspect cases	$28,145,200	+/- $ 6,617,352

APPENDIX C

NON-RESPONDENT ANALYSIS

We tested for the presence of any non-response bias in our coding and medical necessity reviews. For this inspection, a beneficiary for whom we did not obtain supplier documentation is a non-respondent for our coding review; a beneficiary for whom we did not obtain medical records is a non-respondent for our medical necessity review.

CODING REVIEW

To test for non-response bias in our coding review, we obtained information from HCFA's National Claims History 1 percent file for all 500 beneficiaries for whom we requested supplier documentation. We obtained such documentation for 390 beneficiaries. The following table illustrates the number of supplier responses obtained and the response rate by strata

STRATA	NUMBER	RESPONSE RATE
1 ($50 - $100)	112	22%
2 ($501- $1,000)	118	24%
3 (> $1,000)	160	32%

We analyzed three variables for the 500 beneficiaries in our sample - gender, total orthotic claims, and number of devices used. These categorical variables were tested using Chi-square with the appropriate degrees of freedom. In order for the results to be statistically significant at the 95 percent confidence level, the Chi-square value must be higher than 3.84 with 1 degree of freedom.

The results of this analysis are presented in Tables A, B, and C. The Chi-square values given in the tables provide a test of the difference between the distribution of respondents and that of the non-respondents for the variable of interest. Also provided in the tables are the response rates by the different values of the variables.

Table A

GENDER						
	Respondents		**Non-respondents**		**Total**	**Response rate**
Male	147	38%	38	35%	185	79%
Female	243	62%	72	65%	315	77%
Total	**390**		**110**		**500**	**78%**
Chi-square = .365 Degree of freedom = 1						

Table B

CLAIM TOTALS						
	Respondents		**Non-respondents**		**Total**	**Response rate**
< $1,000	229	58%	71	64%	300	76%
> $1,000	161	41%	39	35%	200	80%
Total	**390**		**110**		**500**	**78%**
Chi-square = 1.214 Degree of freedom = 1						

Table C

# OF DEVICES						
	Respondents		**Non-respondents**		**Total**	**Response rate**
1 device	146	37%	55	50%	201	73%
> 1 device	244	62%	55	50%	299	82%
Total	**390**		**110**		**500**	**78%**
Chi-square = 5.634 Degree of freedom = 1						

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Tables A and B show no statistically significant differences between coding review respondents and non-respondents for gender and total orthotic claims.

However, Table C shows a statistically significant difference between respondents and non-respondents with respect to number of devices. In order to test whether this difference introduced any bias, we analyzed the miscoding rate for differences between beneficiaries with 1 device and those with more than 1 device. The miscoding rate differed by 9 percentage points between beneficiaries with 1 device and those with more than 1 device, so further analysis was required. Assuming that non-respondents and respondents from the same group of beneficiaries had the same miscoding rate, we calculated a hypothetical miscoding rate for all 500 beneficiaries in the sample. This calculation gave only a slightly higher miscoding rate of 32 percent (compared to 30 percent for respondents). This difference is not statistically significant.

Given the results of this analysis, we believe that the inspection findings fairly represent the experience of Medicare beneficiaries in our sample.

MEDICAL NECESSITY REVIEW

To test for non-response bias in our medical necessity review, we obtained information from HCFA's National Claims History 1 percent file for all 500 beneficiaries for whom we requested medical records. We obtained such records for 314 beneficiaries. The following table illustrates the number of medical records obtained and the response rate by strata

STRATA	NUMBER	RESPONSE RATE
1 ($50 - $100)	90	29%
2 ($501- $1,000)	95	30%
3 (> $1,000)	129	41%

We analyzed three variables for the 500 beneficiaries in our sample - gender, total orthotic claims, and number of devices used. These categorical variables were tested using Chi-square with the appropriate degrees of freedom. In order for the results to be statistically significant at the 95 percent confidence level, the Chi-square value must be higher than 3.84 with 1 degree of freedom.

The results of this analysis are presented in Tables D, E, and F. The Chi-square values given in the tables provide a test of the difference between the distribution of respondents and that of the non-respondents for the variable of interest. Also provided in the tables are the response rates by the different values of the variables.

Table D

GENDER						
	Respondents		**Non-respondents**		**Total**	**Response rate**
Male	114	36%	71	38%	185	62%
Female	200	64%	115	62%	315	63%
Total	**314**		**186**		**500**	**63%**
Chi-square = .175 Degree of freedom = 1						

Table E

CLAIM TOTALS						
	Respondents		**Non-respondents**		**Total**	**Response rate**
< $1,000	185	59%	115	62%	300	62%
> $1,000	129	41%	71	38%	200	64%
Total	**314**		**186**		**500**	**63%**
Chi-square = .412 Degree of freedom = 1						

Table F

# OF DEVICES						
	Respondents		**Non-respondents**		**Total**	**Response rate**
1 device	126	40%	75	40%	201	63%
> 1 device	188	60%	111	60%	299	63%
Total	**314**		**186**		**500**	**63%**
Chi-square = .002 Degree of freedom = 1						

)))))))))))

Tables D, E, and F show no statistically significant differences between medical review respondents and non-respondents for gender, total orthotic claims, and number of devices.

Given the results of this analysis, we believe that the inspection findings fairly represent the experience of Medicare beneficiaries in our sample.

APPENDIX D

In this appendix, we present in full the comments from the Health Care Financing Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

RECEIVED
2000 FEB 23 PM 3:55
OFFICE OF INSPECTOR GENERAL

The Administrator
Washington, D.C. 20201

DATE: FEB 2 2 2000

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Payments for Orthotics: Inappropriate Payments and Carrier Perspectives," (OEI-02-99-00120 and OEI-02-99-00121)

Thank you for the opportunity to review the above referenced reports. The objectives of these reports are to determine the extent of inappropriate Medicare payments for orthotics and to review carrier policies and procedures and obtain their perspectives on Medicare reimbursement for orthotics. This study is a follow up to a 1997 OIG report entitled "Medicare Orthotics" (OEI-02-95-00380).

Our specific comments are as follows:

OIG Recommendation
HCFA should require suppliers to maintain a description of how custom fabricated and molded devices are made.

HCFA Response
We concur. HCFA agrees that any efforts that can be undertaken to provide better descriptors and/or more efficient billing should be undertaken. However, HCFA feels the current industry guidance, in the form of the American Orthotics and Prosthetics Association's *Illustrated Guide to Orthotics and Prosthetics* will not provide the detail needed. This guide is currently used by the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) and the supplier community and is often described as lacking in detail and not up to date. We feel that when an effort is begun to strengthen the overall billing process for orthotics, a vital part of this effort must be the development of more informative descriptions of orthotic products, their fabrications, and acceptable usage.

IG	
EAIG	
PDIG	
DIG-AS	✓
DIG-EI	
DIG-OI	
DIG-MP	
OCIG	✓
ExecSec	
Date Sent	2-23

OIG Recommendation
HCFA should develop product classification lists for all major groups of orthotic devices.

HCFA Response
We concur. HCFA is in the stages of preparing a program memorandum (PM) that is currently in the Change Management clearance process (Change Request #1083) on one device and will consider developing lists for the other groups on an ongoing basis. This PM instructs the SADMERC to develop and publish a product classification list for Body-jacket code L0430, described as Thoracic-Lumbar-Sacral Orthosis, anterior-posterior-lateral control, with interface material, custom fitted.

OIG Recommendation
HCFA should educate the supplier community.

HCFA Response
We concur. We agree that increased education of the supplier community will enhance their understanding of coding requirements and procedures. To this end, carriers are required to set aside space in each supplier bulletin to DME issues. HCFA will assure that this issue is included in an upcoming bulletin.

OIG Recommendation
HCFA should work with DMERCs to strengthen the billing process for orthotics.

HCFA Response
We concur. HCFA is working to improve the billing processes for orthotics by developing additional screens and edits that require suppliers to submit a patient diagnosis as part of their claim. We are also establishing more specific guidelines for "miscellaneous" codes.

OIG Recommendation
HCFA should require standards for suppliers of custom molded and custom fabricated orthotic devices.

HCFA Response
We concur in part. HCFA is currently working on a proposed rule that will set general provider standards. This proposal should be published in 2000. We do not anticipate issuing standards specific to providers of custom molded and custom fabricated orthotic devices.