MARKETING OF ORTHOTIC BODY JACKETS

MANAGEMENT ADVISORY REPORT

MARCH 1994  OEI-04-92-01081
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To obtain a copy of this report, call the Atlanta Regional Office at (404) 331-5022.
EXECUTIVE SUMMARY

PURPOSE

To describe marketing practices of orthotic body jacket suppliers.

BACKGROUND

In 1993, the Office of Inspector General (OIG) conducted an inspection to determine whether or not Medicare was appropriately billed for orthotic body jackets. We found that

- Medicare claims and allowed charges for orthotic body jackets have increased substantially since 1990, and
- 95 percent of the orthotic body jacket claims paid by Medicare in 1991 under code L0430 were for non-legitimate devices. They did not meet the construction requirements and medical purpose of legitimate body jackets.

While conducting the inspection, we found that many suppliers had questionable marketing practices and billed Medicare for non-legitimate devices.

FINDINGS

Suppliers, Rather Than Physicians, Initiated Orders for Non-Legitimate Body Jackets

Licensed orthotists told us physicians should refer patients needing orthotic body jackets to orthotic suppliers. The orthotists said suppliers should not independently market devices to patients themselves. The suppliers of orthotic body jackets should have licensed orthotists trained to take patients’ measurements and custom-fit devices.

The non-legitimate devices we found in our sample were marketed by Durable Medical Equipment (DME) salespersons before prescriptions or Certificates of Medical Necessity (CMNs) were written by physicians. Typically, DME salespersons marketed their devices for use by nursing home residents. Salespersons presented their products to nursing home directors and physical therapists as restraint alternatives to help patients sit upright in wheelchairs. When a patient agreed to purchase a device, salesmen either completed a CMN or prescription, or gave nursing home staff wording to use and they completed the CMN. The nursing home staff then sent the CMN to a physician for signature. Either the DME salesperson or the nursing home physical therapist, not a trained orthotist, made any adjustments to the device.
Physicians Provided No Control for Preventing Sales of Non-Legitimate Devices

Most physicians of beneficiaries in our sample with non-legitimate devices were not aware of what they had signed a prescription or CMN for. They simply signed prescriptions or CMNs that had been completed either by suppliers or nursing home staff using suppliers’ wording. Twenty-two of 38 physicians who had signed CMNs for non-legitimate devices had never seen the devices. Eleven of the 22 had no record of prescribing any type of device. Most physicians who had seen devices did not realize suppliers had billed Medicare for more sophisticated devices. They assumed suppliers had billed for cushioned wheelchair seating supports rather than custom-fit orthotic body jackets.

CMNs Did Not Assure Medical Necessity

CMNs were signed by physicians even though patient diagnoses and conditions listed on CMNs did not support the need for orthotic body jackets.

Licensed orthotists told us legitimate orthotic body jackets are commonly used to treat injuries to the spine such as vertebra fractures and compression, and to facilitate healing following a surgical procedure on the spine or related tissues.

None of the diagnoses listed on CMNs for non-legitimate devices indicated spinal injuries or surgical procedures. The diagnoses suggested that the patients could have problems sitting upright in wheelchairs, but most conditions were associated with advanced age rather than spinal injuries. Frequently mentioned conditions were dementia, osteoarthritis, Alzheimer's and Parkinson's.

CONCLUSION

To market a non-legitimate device as an orthotic body jacket, DME suppliers took advantage of (1) nursing homes' desires for restraint alternatives, (2) nursing home patients with both Medicare and Medicaid not having to pay for the products, and (3) physicians’ laxity in attention to CMNs they signed. The extent of this practice raises serious questions about the value of CMNs and marketing in nursing homes (95 percent of our sample were non-legitimate devices).

OIG has inspections planned that will study this issue in detail. The inspections will look at (1) the usefulness of CMNs, (2) the appropriateness of payments for equipment, supplies, and professional services provided to beneficiaries in nursing homes, and (3) the role of physicians in controlling patients' medical care.

In the meantime, we suggest that HCFA continue to alert their regional fraud and abuse coordinators and contractors to potential abuse in this area, and advise contractors to exercise diligence in reviewing claims for orthotic body jackets.
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INTRODUCTION

PURPOSE

To describe marketing practices of orthotic body jacket suppliers.

BACKGROUND

In 1993, the Office of Inspector General (OIG) conducted an inspection to determine whether or not Medicare was appropriately billed for orthotic body jackets.¹ The inspection was conducted in response to an allegation from a company which provides Medicare billing services to nursing homes. The allegation was that suppliers were billing Medicare approximately $1,200 per claim for devices consisting of "nothing more than a $50 piece of foam rubber." The bills were submitted to Medicare with a code used for devices described by the Health Care Financing Administration (HCFA) as a "Thoracic Lumbar Sacral Orthosis (TLSO), Anterior-Posterior-Lateral Control (Body Jacket) with interface material custom fitted."

The OIG inspection found that

- Medicare claims and allowed charges for orthotic body jackets have increased substantially since 1990, and

- 95 percent of the orthotic body jacket claims paid by Medicare in 1991 under code L0430 were for non-legitimate devices. They did not meet the construction requirements and medical purpose of legitimate body jackets.

While conducting the study, we found that many suppliers used questionable marketing practices and billed Medicare for non-legitimate devices. Their practices differed from marketing practices of suppliers of legitimate devices. We describe those differences in this Management Advisory Report.

SCOPE

We focused this inspection on marketing practices for devices sold under code L0430 of the HCFA Common Procedure Coding System. Our analysis of 1991 data for all body jacket codes showed that code L0430 had the most significant increase in number of claims. We conducted our inspection between May and October, 1993.

METHODOLOGY

We reviewed a one percent random sample of all Medicare paid claims for code L0430 shown in HCFA’s 1991 Common Working File. Our sample comprised 95 claims.

To determine marketing practices of the suppliers who sold devices to beneficiaries in our sample, we interviewed 46 nursing home administrators. Forty-four of our interviews were by telephone. We also reviewed marketing brochures for all 21 suppliers who had claims appearing in our sample.

To determine how suppliers of legitimate body jackets marketed their devices, we consulted five licensed orthotists, three of whom were members of the American Orthotic and Prosthetic Association (AOPA).

To determine physicians’ awareness of what they had prescribed, we sent questionnaires to the 55 physicians in our sample for whom we had addresses. Medicare requires that body jackets be prescribed by physicians. We got physicians’ addresses from Certificates of Medical Necessity (CMNs) that suppliers submitted with their claims. Sixty-four of the claims in our sample were accompanied by CMNs, and 55 of those CMNs listed the physician’s address. Forty of the 55 (73 percent) responded to our survey.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President’s Council on Integrity and Efficiency.
FINDINGS

Suppliers, Rather Than Physicians, Initiated Orders for Non-Legitimate Body Jackets

The licensed orthotists we interviewed said physicians of patients needing body jackets should refer patients to orthotic suppliers. The orthotists said suppliers should not independently market the devices to patients themselves. Medicare requires that medical necessity exist in order for an orthotic device to be covered by Medicare. The licensed orthotists told us physicians of patients with spinal problems should call orthotic suppliers to order body jackets for their patients. Trained orthotists employed by the suppliers then take patients’ measurements, order devices from manufacturers, and custom-fit the devices to ensure they provide the support needed to stabilize the spine.

Conversely, the non-legitimate devices we found in our sample were marketed by Durable Medical Equipment (DME) salespersons before prescriptions or CMNs were written by physicians. Typically, DME salespersons marketed their devices for use by nursing home residents. Salespersons presented their products to nursing home directors and physical therapists as restraint alternatives to help patients sit upright in wheelchairs. When a patient agreed to purchase a device, the salesperson either completed a CMN or prescription, or gave nursing home staff appropriate wording to use and they completed the CMN form. The nursing home staff then sent the CMN or prescription to a physician for signature. Either the DME salesperson or the nursing home physical therapist, not a trained orthotist, made any adjustments to the device.

This particular marketing strategy was effective because the 1990 Omnibus Budget Reconciliation Act prohibited the use of physical restraints with nursing home patients, and nursing home staff needed alternatives. Further, salespersons pointed out to the nursing home staff and patients’ families that there is no expense to patients covered by Medicaid. Medicare covered 80 percent of the cost and Medicaid the remaining 20 percent.

Physicians Provided No Control For Preventing Sales of Non-Legitimate Devices

Physicians provided no control for assuring the medical need and legitimacy of orthotic body jackets. Most physicians of beneficiaries in our sample with non-legitimate devices were not aware of what they signed a prescription, or CMN, for. They simply signed prescriptions or CMNs that had been completed either by suppliers or nursing home staff using suppliers’ wording. In many instances, physicians never saw the products, and when they did, they did not realize suppliers had billed Medicare for more sophisticated devices. They assumed suppliers had billed for cushioned wheelchair seating supports rather than custom-fit orthotic body jackets.
One physician we surveyed said he was "outraged by the commercialization of the [non-legitimate] product." He had a large nursing home practice, and in one nursing home with approximately 60 patients, he had received 30 to 40 requests for such products. According to the physician, "Salesmen go out and sell the nursing home staff on the product and then believe the doctor will simply sign off."

In our survey, we found that many physicians did simply sign off on suppliers’ orders, and, typically, their patients received non-legitimate devices. Most of the CMNs physicians signed either had the word orthotics or TLSO on the CMN. However, many physicians expressed surprise when we told them Medicare had paid for an orthotic body jacket.

- Of the 40 physicians who had signed CMNs and responded to our survey, 2 had patients with legitimate orthotic devices. Patients of the other 38 physicians received non-legitimate devices.

- Twenty-two of the 38 physicians who had signed CMNs for non-legitimate devices had never seen the devices they had prescribed.

- Eleven of the 22 who had not seen the devices had no record of prescribing any type of device. Two physicians said their patients would have had no need for devices because they were totally bedridden. All the CMNs had signatures, and we did not try to determine if the signatures were those of the physicians or had been forged.

- Of 16 physicians who had seen the devices, 13 described the devices their patients had as cushioned wheelchair supports, which according to the licensed orthotists we interviewed, are not legitimate orthotic body jackets. Yet, these devices were billed to Medicare as custom-fitted body jackets.

- Thirteen of the 16 physicians who had seen the devices said they thought the approximate $900 Medicare allowed for orthotic body jackets (under code L0430) was excessive for the cushioned wheelchair supports received by their patients. One physician said the device his patient had was "unsophisticated, [and] clearly inexpensive to produce."

**CMNs Did Not Assure Medical Necessity**

CMNs provided no control for assuring medical need for orthotic body jackets. CMNs were signed by physicians even though patient diagnoses and conditions listed on the CMNs did not support the need for orthotic body jackets.

The licensed orthotists we interviewed told us legitimate orthotic body jackets are commonly used to treat injuries to the spine such as vertebra fractures and compressions, and to facilitate healing following a surgical procedure on the spine or
related tissues. Diagnoses on the CMNs of the two patients with legitimate body jackets were spinal stenosis (narrowing and constriction of diameter) and compression fracture.

None of the diagnoses listed on the CMNs for non-legitimate devices indicated spinal injuries or surgical procedures. The diagnoses suggested that the patients could have had problems staying upright in wheelchairs, but most conditions were associated with advanced age rather than spinal injuries.

Most CMNs listed more than one diagnosis for each patient. Frequently mentioned conditions were dementia (18 patients), osteoarthritis (12 patients), Alzheimer's and Parkinson's (five patients each). Over three-fourths of the CMNs (55 of 64) listed "lumbar sacral dysfunction" as a primary or secondary diagnosis. None of these conditions normally require an orthotic body jacket, according to the licensed orthotists we interviewed. At least two of the CMNs stated that previous treatment for the patients' conditions had been restraints.

CONCLUSION

To market a non-legitimate device as an orthotic body jacket, DME suppliers took advantage of (1) nursing homes' desires for restraint alternatives, (2) nursing home patients with both Medicare and Medicaid not having to pay for the products, and (3) physicians' laxity in attention to CMNs they signed. The extent of this practice raises serious questions about the value of CMNs and marketing in nursing homes (95 percent of our sample were non-legitimate devices).

OIG has inspections planned that will study this issue in detail. The inspections will look at (1) the usefulness of CMNs, (2) the appropriateness of payments for equipment, supplies, and professional services provided to beneficiaries in nursing homes, and (3) the role of physicians in controlling patients' medical care.

In the meantime, we suggest that HCFA continue to alert their regional fraud and abuse coordinators and contractors to potential abuse in this area, and advise contractors to exercise diligence in reviewing claims for orthotic body jackets.