August 25, 2010

TO: Donald M. Berwick, M.D.
   Administrator
   Centers for Medicare & Medicaid Services

FROM: /George M. Reeb/
   Acting Deputy Inspector General for Audit Services

SUBJECT: Review of Jurisdiction B Medicare Payments for Selected Durable Medical Equipment Claims With the KX Modifier for Calendar Year 2007
(A-05-09-00094)

Attached, for your information, is an advance copy of our final report on Jurisdiction B Medicare payments for selected durable medical equipment claims with the KX modifier for calendar year 2007. We will issue this report to National Government Services, the durable medical equipment Medicare administrative contractor for Jurisdiction B, within 5 business days.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Robert A. Vito, Acting Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Robert.Vito@oig.hhs.gov or James C. Cox, Regional Inspector General for Audit Services, Region V, at (312) 353-2621 or through email at James.Cox@oig.hhs.gov. Please refer to report number A-05-09-00094.

Attachment
August 30, 2010

Report Number: A-05-09-00094

Mr. David Barnett  
Jurisdiction B DME MAC Project Manager  
National Government Services  
8115 Knue Road  
Indianapolis, IN  46250

Dear Mr. Barnett:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled Review of Jurisdiction B Medicare Payments for Selected Durable Medical Equipment Claims With the KX Modifier for Calendar Year 2007. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.


If you have any questions or comments about this report, please do not hesitate to call me, or contact Jaime Saucedo, Audit Manager, at (312) 353-8693 or through email at Jaime.Saucedo@oig.hhs.gov. Please refer to report number A-05-09-00094 in all correspondence.

Sincerely,

/James C. Cox/
Regional Inspector General  
for Audit Services

Enclosure
Direct Reply to HHS Action Official:

Ms. Nanette Foster Reilly  
Consortium Administrator  
Consortium for Financial Management & Fee for Service Operations  
Centers for Medicare & Medicaid Services  
601 East 12\textsuperscript{th} Street, Room 235  
Kansas City, MO  64106
Department of Health & Human Services
OFFICE OF INSPECTOR GENERAL

REVIEW OF JURISDICTION B MEDICARE PAYMENTS FOR SELECTED DURABLE MEDICAL EQUIPMENT CLAIMS WITH THE KX MODIFIER FOR CALENDAR YEAR 2007

Daniel R. Levinson
Inspector General
August 2010
A-05-09-00094
The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health & Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.
EXECUTIVE SUMMARY

BACKGROUND

Pursuant to sections 1832(a)(1) and 1861(n) of the Social Security Act (the Act), Medicare Part B provides for the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Centers for Medicare & Medicaid Services (CMS) contracted with four durable medical equipment Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for DMEPOS. These DME MACs replaced the Durable Medical Equipment Regional Carriers. Also, CMS contracts with Palmetto Government Benefits Administrators, LLC, to serve as the National Supplier Clearinghouse. The National Supplier Clearinghouse is responsible for enrolling and reenrolling DMEPOS suppliers.

Under the statutory and policy framework of the Act, the Medicare National Coverage Determinations Manual defines DME as equipment that can withstand repeated use, serves a medical purpose, is generally not useful to a person in the absence of illness or injury, and is appropriate for use in a patient’s home. For certain DMEPOS, suppliers must use the KX modifier on filed claims. The KX modifier indicates that the claim meets the Medicare coverage criteria and the supplier has the required documentation on file. While suppliers must have a written physician’s order and proof of delivery for all DMEPOS, suppliers must have additional documentation on file for items requiring the KX modifier. For example, respiratory assist devices also require documentation that a sleep study was performed before the date on the physician’s order.


NGS processed approximately $1.9 billion in Medicare DMEPOS claims with calendar year 2007 dates of service. This audit focused on $117,042,423 of Medicare paid claims processed by NGS for therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces (groups 1 and 2) that included the KX modifier.

OBJECTIVE

Our objective was to determine whether the KX modifier was effective in ensuring that suppliers of DMEPOS who submitted claims to NGS had the required supporting documentation on file.

SUMMARY OF FINDINGS

The KX modifier was not effective in ensuring that suppliers of DMEPOS who submitted claims to NGS had the required supporting documentation on file. Of the 100 sampled items, suppliers
had the required documentation on file for 48 items. Suppliers did not have the required
documentation on file for the remaining 52 items. As a result, NGS made unallowable payments
totaling $3,986 for 52 of the 100 sampled items. Based on our sample, we estimated that NGS
paid approximately $55 million to suppliers who did not have the required documentation on file
to support the DMEPOS items with dates of service in 2007.

The types of missing documentation included:

- proof of delivery (28 of 100 items),
- physician’s order (28 of 100 items),
- use or compliant use followup documentation (18 of 78 applicable items),
- sleep study (3 of 78 applicable items), and
- physician’s statement (4 of 22 applicable items).

For 23 of the 52 items, suppliers were missing multiple required documents.

These errors occurred because NGS’s electronic edits in place were not effective for determining
whether suppliers had the required documentation on file when they used the KX modifier on
claims. The edits could only determine whether the required KX modifier was on the claim.

RECOMMENDATIONS

We recommend that NGS:

- recover the $3,986 in payments for specific DMEPOS items claimed for which the
  suppliers did not have the required documentation,
- review other payments for DMEPOS related to our unallowable sample items and recover
  any additional unallowable payments,
- notify CMS of the 28 suppliers who did not meet the supplier standard for maintaining
  proof of delivery so CMS can take appropriate action, and
- develop a corrective action plan to improve the effectiveness of the KX modifier and
  potentially save an estimated $55 million.

AUDITEE COMMENTS

In written comments on our draft report, NGS concurred with our recommendations. NGS stated
that it recognized that there are many challenges in addressing the problems with the KX
modifier. Nevertheless, NGS stated that it was committed to using its available resources to
assure that it meets coverage criteria and documentation requirements in its medical policies. NGS’s comments are included in their entirety as Appendix D.
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INTRODUCTION

BACKGROUND

The Medicare program, established by Title XVIII of the Social Security Act (the Act) in 1965 provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. Pursuant to sections 1832(a)(1) and 1861(n) of the Act, Medicare Part B provides for the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS contracted with four durable medical equipment Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for DMEPOS. These DME MACs replaced the Durable Medical Equipment Regional Carriers. Also, CMS contracts with Palmetto Governmental Benefits Administrators, LLC, to serve as the National Supplier Clearinghouse. The National Supplier Clearinghouse is responsible for enrolling and reenrolling DMEPOS suppliers. CMS will revoke a supplier’s billing privileges if it finds that the supplier does not meet the supplier standards (42 CFR § 424.57(c) and (d)).

Contracts for Processing Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Claims


KX Modifier Used for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Claims Processing

National Coverage Determinations (NCD) describe the circumstances for Medicare coverage nationwide for specific medical service procedures or devices including DMEPOS and generally outline the conditions under which a service or device is considered covered. The Medicare National Coverage Determinations Manual (Pub. No. 100-03, chapter 1, section 280.1) defines DMEPOS as equipment that can withstand repeated use, serves a medical purpose, is generally not useful to a person in the absence of illness or injury, and is appropriate for use in a patient’s home.

Contractors develop supplier manuals, Local Coverage Determinations (LCD), and Policy Articles for covered DMEPOS items. These materials specify under what clinical circumstances the DMEPOS item is considered to be reasonable and necessary. For covered DMEPOS items (including therapeutic shoes for diabetics (therapeutics shoes), continuous positive airway

1 Federal requirements referenced in this document were in effect during our audit period.
pressure systems (CPAP), respiratory assist devices (RAD), and pressure reducing support surfaces (groups 1 and 2) (PRSS))\(^2\), the LCDs require a KX modifier be added to the claims before they can be paid. By adding the KX modifier, the supplier attests that the claim meets the Medicare coverage criteria and that the specific required documentation, which varies based on the DMEPOS item, is on file at the supplier before submitting the claim to the DME MAC. This documentation requirement includes the written physician’s order and proof of delivery that are required for all DMEPOS, as well as additional documentation such as a sleep study for a RAD claim.

Through supplier manuals, LCDs, and Internet postings, the contractors instructed the suppliers to use the KX modifier only if the suppliers have the required documentation on file. However, if the KX modifier is not used with claims for DMEPOS that require it, the claims will be denied.

This audit focused on Medicare claims paid by NGS for therapeutic shoes, CPAPs, RADs, and PRSS.

**Documentation Requirements for Selected Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Requiring the KX Modifier**

<table>
<thead>
<tr>
<th>Documentation Required to be on File at Supplier</th>
<th>Required by</th>
<th>Therapeutic Shoes</th>
<th>CPAP</th>
<th>RAD</th>
<th>PRSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician’s Order (written, signed, and dated)</td>
<td>- <em>Program Integrity Manual</em> (PIM), Pub. No. 100-08, chapter 5 - LCDs</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Proof of Delivery</td>
<td>- 42 CFR § 424.57(c)(12) - PIM, chapter 4</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Polysomnography (sleep study) Before Physician’s Order</td>
<td>- NCD - LCDs</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Use or Compliant Use Followup Statement of Physician and/or Beneficiary</td>
<td>- LCDs</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^2\) These DMEPOS are included in the Level II Healthcare Common Procedure Coding System, which is a comprehensive, standardized system that classifies similar medical products into categories for efficient claims processing. It is the standardized coding system used for describing, identifying, and preparing claims for DMEPOS.
OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the KX modifier was effective in ensuring that suppliers of DMEPOS who submitted claims to NGS had the required supporting documentation on file.

Scope

NGS processed approximately $1.9 billion in Medicare DMEPOS claims in Jurisdiction B with calendar year 2007 dates of service. This audit focused on $117,042,423 of these Medicare paid claims for therapeutic shoes, CPAPs, RADs, and PRSS that included the KX modifier.

We limited our review of internal controls to gaining an understanding of NGS’s processing of selected DMEPOS claims that were submitted with the KX modifier. We did not determine whether the sample items met other Medicare coverage criteria, such as medical necessity.

From September 2009 through January 2010, we conducted fieldwork at NGS’s offices in Indianapolis, Indiana, and at suppliers’ offices in seven States.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed NGS officials concerning the manual and electronic claims processing procedures for claims for therapeutic shoes, CPAPs, RADs, and PRSS with the KX modifier and NGS’s edits in the claims processing system to ensure that claims were adjudicated;
- interviewed NGS officials concerning the education and training specific to the KX modifier that NGS provided to the suppliers of therapeutic shoes, CPAPs, RADs, and PRSS;
- selected a simple random sample of 100 items from four categories of DMEPOS (Appendix A);
- made unannounced visits to the 90 suppliers to obtain their documentation supporting the use of the KX modifier;
- reviewed the suppliers’ documentation for the sample items to determine whether it met the documentation requirements for using the KX modifier; and

3 Of the 90 suppliers, 7 suppliers had 2 items in the sample, and 3 suppliers were under investigation and not visited.
• requested NGS’s medical review staff review the documentation provided by the suppliers for those sample items that we determined did not meet the documentation requirements for use of the KX modifier.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

The KX modifier was not effective in ensuring that suppliers of DMEPOS who submitted claims to NGS had the required supporting documentation on file. Of the 100 sampled items, suppliers had the required documentation on file for 48 items.\(^4\) Suppliers did not have the required documentation on file for the remaining 52 items. As a result, NGS made unallowable payments totaling $3,986 for 52 of the 100 sampled items. Based on our sample, we estimated that NGS paid approximately $55 million to suppliers who did not have the required documentation on file to support the DMEPOS items with 2007 dates of service.

The types of missing documentation included:

• proof of delivery (28 of 100 items),

• physician’s order (28 of 100 items),

• use or compliant use followup documentation (18 of 78 applicable items),

• sleep study (3 of 78 applicable items), and

• physician’s statement (4 of 22 applicable items).\(^5\)

Additional details on the results of the sampled items are provided in Appendixes B and C.

These errors occurred because NGS’s electronic edits in place were not effective for determining whether suppliers had the required documentation on file when they used the KX modifier on claims. The edits could only determine whether the required KX modifier was on the claim.

\(^4\) Three of the forty-eight sample items were from suppliers who were under investigation, and the sample items were not considered errors.

\(^5\) For 23 of the 52 items, suppliers were missing multiple required documents.
MISSING REQUIRED DOCUMENTATION

Proof of Delivery

Pursuant to the supplier standard (42 CFR § 424.57(c)(12)), the supplier “[m]ust be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery.” Also, the PIM, chapter 4, section 4.26 requires suppliers to maintain proof of delivery documentation in their files for 7 years. Section 4.26.1 outlines proof of delivery requirements for different methods of delivery. Section 4.26 also states that, for “any services, which do not have proof of delivery from the supplier, such claimed items and services shall be denied and overpayments recovered.”

For 28 of the 100 items, suppliers did not have proof of delivery documentation on file to support billing for the DMEPOS. In all 28 instances, at least one of the following deficiencies occurred: the delivery documentation was missing, the delivery documentation was not signed and dated by the beneficiary or his or her designee, or the documentation for shipped items such as tracking numbers or the supplier’s invoice was missing.

Physician’s Order

The PIM, chapter 5, sections 5.2.1 and 5.2.2, state that all DMEPOS suppliers are required to keep on file a physician’s order. The treating physician must sign and date the order. Section 5.2.3 states that if the supplier does not have a written order signed and dated by the treating physician before billing Medicare, the item will be denied.

For 28 of the 100 items, suppliers did not have a physician’s order on file to support billing for the DMEPOS. In all 28 instances, at least one of the following deficiencies occurred: the order was missing, the order was not signed and dated by the physician, or the DMEPOS item was not listed on the order.

Use or Compliant Use Followup Documentation

The LCDs for the CPAP, effective March 1, 2006, June 1, 2007, and July 1, 2007, and the LCDs for the RAD effective April 1, 2006, June 1, 2007, and July 1, 2007, state that, for an E0601 (CPAP) and an E0470 (RAD) to be covered beyond the first 3 months of therapy, the supplier must ascertain no sooner than the 61st day after initiating therapy that the CPAP is being used and that the RAD is being compliantly used. For the CPAP, either the beneficiary or the treating physician must confirm that the beneficiary is continuing to use the CPAP, and the supplier must maintain documentation that the requirement has been met. For the RAD, the supplier must obtain signed statements from both the treating physician and the beneficiary stating that the RAD is being compliantly used.6 The LCDs state that continued coverage of the device will be denied if the requirements are not met.

For 18 of the 78 applicable items in our sample, suppliers did not have the use or compliant use followup documentation on file to support billing for the DMEPOS. In all 18 instances, at least

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6 The LCD defines “compliantly used” for a RAD as an average usage of 4 hours out of 24 hours.
one of the following deficiencies occurred: the use or compliant use followup documentation was missing, the use or compliant use followup was done within 60 days after initiating therapy, the statement(s) required to be completed by the treating physician and/or the beneficiary were missing for the RAD, or the item was billed beyond the first 3 months but before the supplier obtained use or compliant use followup documentation.

**Sleep Study**

The LCDs for the CPAP (E0601), effective March 1, 2006, June 1, 2007, and July 1, 2007, and the RAD (E0470), effective April 1, 2006, June 1, 2007, and July 1, 2007, require that the beneficiary have a documented polysomnographic study. Additionally, polysomnographic studies must not be performed by a DMEPOS supplier.

For 3 of the 78 applicable items, suppliers did not have sleep study documentation on file to support billing for the DMEPOS. In all three instances, the sleep study documentation was missing.

**Physician’s Statement**

Pursuant to the Act, § 1861(s)(12)(A), the physician must certify that the patient meets specific criteria for therapeutic shoes. The LCDs for therapeutic shoes, effective March 1, 2006, June 1, 2007, and July 1, 2007 and the Policy Articles for therapeutic shoes, effective January 1, 2006, June 1, 2007, and July 1, 2007, state that DMEPOS items are covered if the supplier obtains a signed and dated statement from the certifying or treating physician7 saying the patient meets specific criteria. The physician’s statement must be signed and dated some time during the year before the date of service for therapeutic shoes, and the Policy Articles state that the items will be denied if the requirements are not met.

For 4 of the 22 applicable items in our sample requiring a physician’s statement, suppliers did not have the physicians’ statements on file to support billing for the DMEPOS. In all four instances, at least one of the following deficiencies occurred: the physician’s statement of medical need was missing, was incomplete, or was not timely.

**KX MODIFIER SYSTEM EDITS**

The LCDs require DMEPOS suppliers to include the KX modifier on claims submitted for therapeutic shoes, CPAPs, RADs, and PRSS when the “specific required documentation is on file.” Use of the KX modifier constitutes a statement that the suppliers have the documentation on file that the policy requires for the particular item or service.

NGS established electronic edits to evaluate claims submitted by the DMEPOS suppliers. However, the edits were not effective for determining whether suppliers had the required documentation on file when they used the KX modifier on claims. The edits could only determine whether the required KX modifier was on the claim.

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7 The certifying or treating physician is the physician who treats the underlying condition that requires the use of the DMEPOS.
EFFECT OF UNALLOWABLE PAYMENTS

For 52 of the 100 items in our sample, suppliers who did not have the required documentation on file to support their use of the KX modifier received $3,986 in payments. Based on our sample, we estimated that NGS paid approximately $55 million in unallowable Medicare payments to DMEPOS suppliers with 2007 dates of service.

RECOMMENDATIONS

We recommend that NGS:

• recover the $3,986 in payments for specific DMEPOS items claimed for which the suppliers did not have the required documentation,

• review other payments for DMEPOS related to our unallowable sample items and recover any additional unallowable payments,

• notify CMS of the 28 suppliers who did not meet the supplier standard for maintaining proof of delivery so CMS can take appropriate action, and

• develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated $55 million.

AUDITEE COMMENTS

In written comments on our draft report, NGS concurred with our recommendations. NGS stated that it recognized that there are many challenges in addressing the problems with the KX modifier. These problems are well known to the DME MACs and have been highlighted in other Office of Inspector General reports as well as multiple medical review audits conducted by NGS. Additionally, NGS stated that there is a large volume of claims using the KX modifier and focusing on these claims would require them to forego review of claims that ranked higher in their medical review prioritization.

Nevertheless, NGS stated that it was committed to using its available resources to assure that it meets coverage criteria and documentation requirements in its medical policies. NGS will review its current provider outreach and education plan, assess compliance as dictated by its medical review strategy, discuss with CMS the availability of additional funding to expand its current activities, and explore collaboration with other DME MACs on plans to address problems with usage of the KX modifier.

NGS’s comments are included in their entirety as Appendix D.
APPENDIXES
APPENDIX A: SAMPLING METHODOLOGY

POPULATION

The population consisted of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items for the year ending December 31, 2007, that DMEPOS suppliers claimed for payment using the KX modifier under Medicare Part B.

SAMPLING FRAME

The sampling frame consisted of 1,390,415 items totaling $117,042,423 for the year ending December 31, 2007. These items were for specific categories of DMEPOS (therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces (groups 1 and 2)) claimed for payment using the KX modifier under Medicare Part B.

SAMPLE UNIT

The sample unit was a line item.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

We selected a sample of 100 line items.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the Office of the Inspector General (OIG), Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sampling frame. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used OIG/OAS statistical software to estimate the amount of potentially unallowable payments.
## APPENDIX B: SAMPLE RESULTS AND ESTIMATES

### SAMPLE RESULTS

<table>
<thead>
<tr>
<th>Frame Size</th>
<th>Frame Value</th>
<th>Sample Size</th>
<th>Value of Sample</th>
<th>Number of Unallowable Payments</th>
<th>Value of Unallowable Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,390,415</td>
<td>$117,042,423</td>
<td>100</td>
<td>$7,992</td>
<td>52</td>
<td>$3,986</td>
</tr>
</tbody>
</table>

### ESTIMATES OF UNALLOWABLE PAYMENTS
*(Limits Calculated for a 90-Percent Confidence Interval)*

<table>
<thead>
<tr>
<th></th>
<th>Total Estimated Unallowable Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point estimate</td>
<td>$55,422,915</td>
</tr>
<tr>
<td>Lower limit</td>
<td>43,750,627</td>
</tr>
<tr>
<td>Upper limit</td>
<td>67,095,204</td>
</tr>
</tbody>
</table>
### APPENDIX C: ERROR DETAILS

#### TYPES OF MISSING DOCUMENTATION

<table>
<thead>
<tr>
<th>Types of Missing Documentation</th>
<th>DMEPOS Required for</th>
<th>Total in Sample</th>
<th>Total Number of Errors</th>
<th>CPAP Related Errors</th>
<th>TS* Related Errors</th>
<th>RAD Related Errors</th>
<th>PRSS Related Errors</th>
<th>Line Items With Only One Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proof of Delivery</td>
<td>All</td>
<td>100</td>
<td>28</td>
<td>19</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Physician’s Prescription/Order</td>
<td>All</td>
<td>100</td>
<td>28</td>
<td>18</td>
<td>8</td>
<td>2</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>Use or Compliant Use Followup Documentation</td>
<td>CPAP/RAD</td>
<td>78</td>
<td>18</td>
<td>12</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Sleep Study</td>
<td>CPAP/RAD</td>
<td>78</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Physician’s Statement</td>
<td>TS, PRSS</td>
<td>22</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Total Errors (Duplicated Count)  81  52  18  11  0  29

#### CATEGORIES OF DURABLE MEDICAL EQUIPMENT

<table>
<thead>
<tr>
<th>Categories of Durable Medical Equipment</th>
<th>Dollars Tested</th>
<th>Items Tested</th>
<th>Items Allowed</th>
<th>Items Errors</th>
<th>Dollars in Error</th>
<th>1 Error</th>
<th>2 Errors</th>
<th>3 Errors</th>
<th>Multiple Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous Positive Airway Pressure Systems</td>
<td>$4,394.77</td>
<td>66</td>
<td>32</td>
<td>34</td>
<td>$2,540.47</td>
<td>19</td>
<td>12</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Therapeutic Shoes for Diabetics</td>
<td>2,405.62</td>
<td>22</td>
<td>11</td>
<td>11</td>
<td>1,104.07</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Respiratory Assist Devices</td>
<td>1,191.66</td>
<td>12</td>
<td>5</td>
<td>7</td>
<td>341.53</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Pressure Reducing Support Surfaces (groups 1 and 2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Totals  $7,992.05  100  48  52  $3,986.07  29  17  6  23

*Therapeutic shoes are a one-time purchase.
†Three of these forty-eight sample items were for suppliers who were under investigation.
‡Twenty-three of the fifty-two unallowable sampled items had multiple errors.

CPAP = continuous positive airway pressure systems
TS = therapeutic shoes for diabetics
RAD = respiratory assist devices
PRSS = pressure reducing support surfaces (groups 1 and 2)
TO: Mr. James C. Cox, Regional Inspector General for Audit Services
FROM: Mr. David Barnett, Project Manager Jurisdiction B DME MAC
Date: July 6, 2010

Thank you for the opportunity to review and comment on the above-referenced OIG draft report.

The KX modifier is added to claims submitted to the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) when the requirements specified in a Local Coverage Determination (LCD) have been met. Most commonly it is used as an attestation by the supplier that the coverage criteria for the durable medical equipment, orthotics, prosthetics or supplies (DMEPOS) item being billed have been met.

The OIG reviewed 100 claims with dates of service in 2007 that were processed by National Government Services (NGS), the Jurisdiction B DME MAC, for therapeutic shoes for diabetics, continuous positive airway pressure (CPAP) systems, respiratory assist devices (RAD), and pressure reducing support surfaces (groups 1 and 2) and that included the KX modifier. They found that 52% of the sampled claims did not have all of the documentation required to support coverage of the item.

OIG Recommendations

The OIG recommended that NGS:

- Recover the $3,986 in payments for specific DMEPOS items claimed for which the suppliers did not have the required documentation,
- Review other payments for DMEPOS related to their unallowable sample items and recover any additional unallowable payments,
- Notify CMS of the 28 suppliers who did not meet the supplier standard for maintaining proof of delivery so CMS can take appropriate action, and
- Develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated $55 million.
NGS Response

Problems that are associated with the use of the KX modifier are well known to the DME MACs. The lack of documentation to support use of the KX modifier has been highlighted in other OIG reports on specific medical policies including those on support surfaces (1997 and 2009), therapeutic shoes (1998), and negative pressure wound therapy pumps (2007). These reports identified problems on a national level among all DME contractors, which is to be expected considering the large number of national or regional suppliers. During the course of multiple medical review audits conducted by NGS, we have also found that documentation verifying that the coverage criteria have been met is often not present for claims on which the supplier has used the KX modifier. In particular, over the past year, we have conducted audits on therapeutic shoes, CPAP devices, and group 2 support surfaces with results similar to those found by the OIG.

In order to formulate a response to the problems identified in the OIG report, it is important to understand the scope of the issue and resources that are available to the DME MAC.

The Jurisdiction B DME MAC is projected to receive approximately 15 million claims in calendar year 2010. Over 99% of those claims will be sent electronically without. When submitting an electronic claim, it is not possible for the supplier to include the documents that would verify that all of the coverage criteria and documentation requirements had been met. Even on the 1% of claims that are received hard copy, the supplier is not required to include all of the documents required to support coverage of the claim. The only way for the DME MAC to conduct a review similar to that performed by the OIG is to send an Additional Documentation Request (ADR) letter to the supplier asking for documentation related to the claim and then perform complex manual medical review.

In the first quarter of 2010, NGS received approximately 1 million claims with a KX modifier. Projecting this to the full year, results in an estimate that the Jurisdiction B DME MAC will receive approximately 4 million claims with a KX modifier in 2010. NGS is funded to perform complex manual medical review on less than 1% of that number of claims this year. NGS would not be able to review all, or even a significant percentage of the KX modifier claims, unless CMS provided additional funding.

Furthermore, there are many DME MAC medical policies that do not use the KX modifier as an attestation that coverage criteria have been met, including but not limited to, Glucose Monitors, Oxygen, Surgical Dressings, and Nebulizers (except for one specific, low volume drug). Data analysis drives our medical review strategy, establishing our priorities for using our limited medical review resources. Focusing our review on KX modifier claims would require us to forego review of claims that ranked higher in our medical review prioritization.
NGS is aware of the problems with the use of the KX modifier. However, considering the limited information concerning medical necessity that can be submitted electronically with a claim and our ability to perform manual review on only a small fraction of claims, it does have some value. If the supplier determines that the coverage criteria have not been met and therefore does not add the KX modifier to the claim, the claim will be denied by an automated edit. Without the KX modifier option, all of those claims would otherwise be paid.

Although there are many challenges in addressing the problems with the KX modifier identified in the OIG report, NGS is committed to using the resources that are available to assure that coverage criteria and documentation requirements in our medical policies are met.

NGS concurs with the specific OIG recommendations:

- NGS will recover the $3,986 in payments for specific DMEPOS items identified in the OIG report.
- Concerning related items, for those devices that are rented (i.e., CPAP, RAD, and support surfaces), NGS will recover payments made for other rental months for those beneficiaries. For devices that have related accessories (i.e., CPAP and RAD), NGS will also recover overpayments made for those accessories.
- NGS will notify CMS of the 28 suppliers who did not meet proof of delivery requirements.
- Concerning an action plan to address problems with the KX modifier, NGS will:
  o Review our current Provider Outreach and Education (POE) plan to assure that correct usage of the KX modifier is emphasized in our presentations, web-based training, and other educational interventions;
  o Assess compliance during the course of complex manual medical review of KX modifier claims that are dictated by our Medical Review Strategy;
  o Discuss with CMS the availability of additional funding to expand our current POE and MR activities;
  o Explore collaboration with the other DME MACs on plans to address problems with usage of the KX modifier.

Sincerely,

David Barnett
Project Manager, Jurisdiction B DME MAC