Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PAYMENTS FOR NEGATIVE PRESSURE WOUND THERAPY PUMPS IN 2004

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EXECUTIVE SUMMARY

OBJECTIVE

To determine the extent to which claims for negative pressure wound therapy pumps (the pump) met Medicare coverage criteria and supplier documentation requirements in 2004.

BACKGROUND

The pump is a portable or stationary device used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. Medicare covers the pump and its supplies under Part B as durable medical equipment.

Medicare-allowed payments for the pump increased 444 percent between 2001 and 2005, from $25 million to $136 million. This increase raises concerns about whether the pump is being prescribed appropriately in accordance with Medicare coverage criteria.

This study is based on a medical review of a random sample of 378 pump claims from the Centers for Medicare & Medicaid Services' (CMS) National Claims History file that had a date of service in 2004. Registered nurses with experience in wound care reviewed the medical records for these claims to determine whether they met Medicare coverage criteria.

We also conducted a separate review of the documentation provided by the supplier to determine whether each claim met Medicare supplier documentation requirements. The reviewers also determined whether the information on the forms provided by the supplier, i.e. supplier-prepared statements, was supported by the information in the medical record. Lastly, we interviewed staff from the four Durable Medical Equipment Regional Carriers (DMERC) and the Statistical Analysis Durable Medical Equipment Regional Carrier.

FINDINGS

Almost one-quarter of pump claims in 2004 did not meet Medicare coverage criteria, resulting in approximately $21 million in improper payments. Medicare allowed $90 million in 2004 for pumps. Based on an independent review of medical records, 24 percent of the claims for these pumps did not meet Medicare coverage criteria, resulting in an

estimated $21 million in improper payments in 2004. An additional $6 million in improper payments were made for supplies associated with these claims.

Reviewers determined that 15 percent of all pump claims in 2004 did not have sufficient documentation to determine whether the claims met Medicare coverage criteria. Another 6 percent of all pump claims were undocumented, while an additional 3 percent were not medically necessary.

Virtually all pump claims met supplier documentation requirements. About 2 percent of claims in 2004 did not meet supplier documentation requirements. In these cases, the supplier did not provide proof of delivery, or the supplier did not have a record of providing the pump to the patient on the date of service in our sample. For all other claims, the supplier had a signed and dated order by the treating physician and proof of delivery.

For 44 percent of the claims, the information on the supplier-prepared statement was not fully supported by the medical record. Supplier-prepared statements are forms that are completed by the physician or treating clinician that contain clinical information relating to the initial order or continued rental of the pump. Medicare policy states that there must be information in the medical record to substantiate information provided on a supplier-prepared statement.

For 44 percent of the claims that had a supplier-prepared statement and a medical record, the reviewers determined that the information on the statement was not fully supported by the medical record. Additionally, the reviewers found discrepancies between the medical record and the supplier-prepared statement for 7 percent of the claims.

DMERCs had some safeguards in place to prevent improper payments. Based on our interviews with staff at each of the DMERCs, we found that all four DMERCs had some safeguards in place to prevent or recoup improper payments for pump claims. Staff at all four DMERCs reported conducting medical reviews of pump claims, although their approaches differed. Two DMERCs focused their reviews solely on claims for the fifth and successive months of pump use. One DMERC reviewed only the supplier-prepared statements.

RECOMMENDATIONS

Based on the results of our review, we recommend that CMS ensure that claims for the pump meet Medicare coverage criteria and are paid appropriately. To accomplish this, CMS should conduct additional medical reviews of pump claims that are based on the medical record and not only the supplier-prepared statement. CMS should also educate suppliers and wound care providers about the appropriate use of the pump and what needs to be documented in the medical record.

In addition, CMS should consider the following options to address this recommendation. CMS should consider establishing advance coverage determinations of pump claims from suppliers that have a high number of claims that have been denied or have a pattern of overutilization. CMS should consider requiring a face-to-face examination of the patient by the physician and/or requiring the supplier to obtain from the physician pertinent parts of the patient's medical record that clearly support the medical necessity of the pump. Lastly, CMS should consider strengthening the coverage criteria for the pump and increasing prepayment reviews of these claims.

In addition to these recommendations, we forwarded information on the insufficiently documented, undocumented, and medically unnecessary claims identified in our sample to CMS for appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurs with our three recommendations to ensure that claims for the pump meet Medicare coverage criteria and are paid appropriately. CMS states that it will work with its contractors to: (1) prioritize medical reviews of pump claims with other high-risk services, (2) require that medical reviews of pump claims be based on the entire medical record, and (3) direct its contractors to develop an education article based on our findings. It does not concur with the five additional options we recommended for consideration. We understand CMS's concerns that implementing some of our options may impose delays in the provision of the pump. However, we continue to recommend that CMS consider the third option—requiring the supplier to obtain pertinent parts of the patient's medical record prior to submitting a claim—as an important mechanism to curb inappropriate payments.

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INTRODUCTION

OBJECTIVE

To determine the extent to which claims for negative pressure wound therapy pumps (the pump) met Medicare coverage criteria and supplier documentation requirements in 2004.

BACKGROUND

The pump is a portable or stationary device used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. The device applies controlled negative or subatmospheric pressure to the affected site and assists in removing fluid, increasing blood flow to the site, and stimulating the growth of granulation tissue.[1]

Utilization of the pump has increased dramatically in recent years. Medicare-allowed payments for the rental of the pump increased 444 percent between 2001 and 2005, from $25 million to $136 million.[2] This increase raises concerns about whether the pump is being prescribed appropriately in accordance with Medicare coverage criteria.

The Negative Pressure Wound Therapy Pump

Medicare covers the pump under Part B as durable medical equipment (DME).[3] The pump is classified as a capped rental item and can be billed on a monthly basis for up to 4 months, as long as it is considered medically necessary. In certain circumstances, a physician may request an extension after the fourth month. Medicare pays the same amount for the first month as it does for each subsequent month; Medicare payments for the pump averaged about $1,673 per month in 2005.[4]

Medicare also covers two types of supplies used in conjunction with the pump. It covers a specialized dressing set that creates a seal around the wound site to maintain subatmospheric pressure. This dressing set

[1] Granulation tissue is a specialized tissue that is rich in tiny blood vessels and is created by the body as a response to injury.

[2] Based on data from the Centers for Medicare & Medicaid Services's National Claims History file. Allowed dollars for the pump totaled $90 million in 2004, the year from which we drew our sampled claims for this study.

[3] The DME is defined as equipment furnished by a supplier or a home health agency that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to an individual in the absence of an illness or injury, and is appropriate for use in the home (42 CFR § 414.202).

[4] Medicare allowances for the pump vary by State.

includes a resilient open-cell foam surface dressing, drainage tubing, and an occlusive dressing.[5] Medicare also covers a canister that collects the drainage of fluids from the wound. The Centers for Medicare & Medicaid Services (CMS) added the pump and its supplies to its list of Medicare-covered DME on October 1, 2000.

As it does with most DME items, the supplier bills Medicare for the pump and its associated supplies. If a physician determines that the pump is medically necessary, the physician writes a prescription for the pump and provides it to the supplier. The supplier delivers the item to the beneficiary and bills Medicare on a monthly basis for the use of the pump in the subsequent month.

At the time of our review, one company manufactured and supplied the pump that was approved for billing under Medicare. This supplier was responsible for billing 99.6 percent of all pump claims in 2004.[6] In 2005, another pump was approved for billing under Medicare, and now multiple suppliers may bill Medicare for the pump.

Medicare Coverage Criteria

General provisions of the Social Security Act (the Act) govern Medicare reimbursement for all services, including pumps.

- Section 1862(a)(1)(A) of the Act states that no payment may be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[7]
- Section 1833(e) of the Act requires that providers furnish "such information as may be necessary in order to determine the amounts due" to receive Medicare payment.[8]

Regulations that reflect these provisions of Medicare law appear at 42 CFR §§ 411.15 and 424.5(a)(6).

Coverage criteria for the pump are found in the Local Medical Review Policy (LMRP), entitled "LMRP for Negative Pressure Wound Therapy Pumps." LMRPs issued by each Durable Medical Equipment Regional Carrier (DMERC) are identical and include criteria for "reasonable and

[5] Occlusive dressing seals the wound completely to prevent infection and to prevent moisture from escaping through the dressing.

[6] The remaining claims were billed in error by other suppliers.

[7] 42 U.S.C. §1395y(a)(1)(A).

[8] 42 U.S.C. §1395l(e).

necessary" that are described below.[9] One of the LMRPs is included in Appendix A.

The LMRP includes specific criteria for initial and continued coverage of the pump and its supplies. To receive initial coverage, the patient must have a certain type of ulcer or wound. Also, a complete wound therapy program should have been addressed prior to the application of the pump. For all ulcers and wounds, this therapy program must include several general measures, such as "documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional."[10]

For continued coverage, a licensed medical professional must, on a regular basis, directly assess the wound(s) being treated with the pump and supervise or directly perform the dressing change.[11] On at least a monthly basis, a licensed medical professional must document changes in the ulcer's dimensions and characteristics.[12] The LMRP also states that the pump and its supplies will not be covered under certain circumstances, such as instances in which there has not been any measurable degree of wound healing in the prior month.[13]

Supplier Documentation Requirements

The "Medicare Program Integrity Manual" requires that to submit a claim for DME, the supplier must keep on file a number of documents.[14] For the pump, we focused on the requirements that the supplier must have a written physician's order and must maintain proof of delivery

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[9] Effective December 7, 2003, CMS contractors began converting existing LMRPs into Local Coverage Determinations. The difference between LMRPs and Local Coverage Determinations is that Local Coverage Determinations consist only of reasonable and necessary information, while LMRPs may also contain other provisions. The LMRP that covered service dates in 2004 has now been converted to "LCD for Negative Pressure Wound Therapy Pumps," effective date July 1, 2006. Available online at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5008&lcd_version=20&show=all. Accessed on November 7, 2006.

[10] The policy also states that the pump will be denied at any time as not medically necessary under certain circumstances, such as the presence of a fistula to an organ or body cavity within the vicinity of the wound.

[11] This criterion can be found in the Continued Coverage section of the LMRP. Available online at http://coverage.cms.fu.com/mcd%5Farchive/search.asp. Accessed on August 24, 2005.

[12] Ibid.

[13] Coverage beyond 4 months is given individual consideration based on additional required documentation.

[14] CMS, "Medicare Program Integrity Manual," chapter 5, section 2.1, Rev. 30, September 27, 2002.

documentation.[15] In addition, the supplier may not dispense any DME until it has obtained a written order.[16]

The LMRP includes more specific supplier documentation requirements for the pump. It states that the supplier of the pump and supplies must obtain from the treating clinician an assessment of wound healing progress, based upon the wound measurements as documented in the patient's medical record, to determine whether the equipment and supplies continue to qualify for Medicare coverage.[17] Additionally, during 2004, the LMRP required that for the fifth and successive months, the supplier must include additional documentation with the claim.

Supplier-Prepared Statements

To meet Medicare requirements, the supplier of the pump developed a series of forms that are completed by the physician or the treating clinician to determine whether Medicare coverage criteria are met. These forms are supplier-prepared statements and include a series of checkoff boxes that closely follow the criteria specified in the LMRP. The forms include a prescription form, a clinical form, and a patient demographic form. The supplier also has a wound progress form that the clinician completes each month that the pump is used and another form that is completed if the pump is used beyond the fourth month.

The "Medicare Program Integrity Manual" states that the supplier-prepared statement by itself is not sufficient documentation of medical necessity. It further states that there must be information in the patient's medical record that supports the medical necessity of the item and the information on the supplier-prepared statement.[18]

Medical Record

Both the "Medicare Program Integrity Manual" and the LMRP state that the patient's medical records must contain sufficient

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[15] CMS, "Medicare Program Integrity Manual," chapter 5, section 2.1, Rev. 30, September 27, 2002.

[16] CMS, "Medicare Program Integrity Manual," chapter 5, section 1.1, Rev. 3, November 22, 2000.

[17] Suppliers must add a KX modifier when they bill for the pump if the coverage criteria have been met. If the coverage criteria are not met, the supplier may submit additional documentation with the claim to justify coverage. The KX modifier is used for both initial and continued claims.

[18] CMS, "Medicare Program Integrity Manual," chapter 5, section 2, Rev. 3, November 22, 2000.

documentation of medical necessity and may include physician, hospital, nursing home, home health agency (HHA), and records from other health care professionals.[19] The "Medicare Program Integrity Manual" further requires that if the medical record does not support the medical necessity for the item, the supplier may be liable for the dollar amount involved.[20]

In addition, the LMRP specifies that the medical record must include documentation of the history, previous treatment regimens, and current wound management for which the pump is being billed. Documentation must indicate regular evaluation and treatment of the patient's wounds. Documentation of measurements of wound characteristics indicating healing progress must be entered at least monthly.[21]

Claims Processing

At the time of the study, four DMERCs were responsible for processing and paying all DME claims. The Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) was responsible for identifying billing trends and offering guidance to suppliers on billing.

In 2006, the DMERC functions were transferred to DME Medicare Administrative Contractors (MAC) and program safeguard contractors (PSC). MACs process claims and conduct provider outreach and education, while PSCs conduct program safeguard activities, including medical reviews and fraud investigations. Also, CMS, through its Provider Communications Group, works with MACs on a national level to educate providers on various issues, such as billing.

METHODOLOGY

We based this study on data from several sources: (1) a medical record review of a random sample of pump claims, (2) a review of supplier documentation for these claims, and (3) interviews with staff at the four DMERCs and the SADMERC. A detailed description of the methodology is provided in Appendix B.

[19] CMS, "Medicare Program Integrity Manual," chapter 5, section 2, Rev. 3, issued November 22, 2000; "LMRP for Negative Pressure Wound Therapy Pumps (L5008)," Documentation Requirements.

[20] CMS, "Medicare Program Integrity Manual," chapter 5, section 2.1, Rev. 30, September 27, 2002.

[21] This criterion can be found in the Documentation Requirements section of the LMRP. Available online at http://coverage.cms.fu.com/mcd%5Farchive/search.asp. Accessed on August 24, 2005.

For the medical review, we selected a simple random sample of 400 pump claims from CMS's National Claims History file that had a service date in 2004. We excluded one claim from our sample because of an ongoing investigation by the Office of Inspector General. Fifty-eight percent of the remaining 399 claims were for the initial month, and 42 percent were for subsequent months.

Our review was based on 378 of the 399 claims in our sample, for a response rate of 95 percent. We did not include 21 claims in our analysis because we were unable to locate current addresses for the providers, we received the records after the review was conducted, or the record was missing some specific information that may have been found in another provider's medical record, which we were unable to obtain in our study timeframe.

We requested the medical records from the physician who prescribed the pump and any HHAs and/or skilled nursing facilities (SNF) that billed Medicare for services provided to the beneficiary on the sampled claim. We included the medical records from these providers because they may have documentation about the wounds for which the pumps were being billed.

We used a contractor to conduct the medical review. The reviewers included three registered nurses, each of whom had at least 5 years of wound care experience. The reviewers used a standardized instrument to review the medical record and determine whether each sampled claim met Medicare coverage criteria. The objective of the review was to determine whether the medical record substantiated the claim. The reviewers did not refer to the supplier-prepared statements in determining whether the medical record supported the claim.

We analyzed the data from the medical review to determine the proportion of claims that did not meet Medicare coverage criteria. We looked for differences between the error rates for initial claims and continued claims. We also identified the supplies associated with the inappropriate pump claims that were billed within 30 days after the service date of the pump claim. We reasoned that if the pump claim were inappropriate, any supplies billed during this time period were also inappropriate. We calculated the total dollars paid in error for the pump claims and the associated supplies.

In collaboration with the reviewers, we conducted a separate review of the documentation provided by the supplier. To accomplish this, we requested all of the documentation from the supplier related to each of

the sampled claims. The supplier provided documentation for 396 of the 399 claims in our sample. This documentation usually consisted of proof-of-delivery receipts and supplier-prepared statements such as monthly progress forms.

We reviewed the documentation to determine whether it met Medicare supplier documentation requirements. Specifically, we determined whether there was a signed and dated physician order, proof of delivery, and additional documentation for claims that extended beyond 4 months. The contractor then reviewed the supplier-prepared statement for each claim to determine whether the information on the statement was supported by the medical record.

Lastly, we interviewed staff at all four DMERCs and at the SADMERC. Our questions focused on the types of program safeguards each DMERC had in place to prevent and recoup improper payments for pump claims.

Standards

Our review was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

Almost one-quarter of pump claims in 2004 did not meet Medicare coverage criteria, resulting in approximately $21 million in improper payments

Medicare allowed $90 million in 2004 for wound therapy pumps. Based on an independent review of medical records, 24 percent of the claims for these pumps did not meet Medicare coverage criteria, resulting in an estimated $21 million in improper payments in 2004. The majority of these improper payments were for claims with insufficient documentation. There was no statistically significant difference in the overall error rate between claims for initial coverage and claims for continued coverage. Table 1 below describes the error rates and the estimated dollars paid in error. Appendix C provides the confidence intervals for the key estimates.

An additional $6 million in improper payments were made for supplies associated with the pump claims that did not meet Medicare coverage criteria. Medicare pays for supplies, including canisters and wound dressings, that are used in conjunction with the pump. These improper payments were for supplies that were billed within 30 days after the service date of the pump claims that did not meet Medicare coverage criteria.

Table 1: Coverage and Documentation Errors for Negative Pressure Wound Therapy Pumps, 2004

Type of Error	Claims	Allowed Amount
Insufficient documentation	14.8%	$12,800,567
Undocumented	5.8%	$4,993,943
Medically unnecessary	3.4%	$2,927,484
Total Errors	24.1% *	$20,721,994

* Total does not equal the sum of individual rows because of rounding.

Source: Office of Inspector General medical review results, 2006.

Insufficient documentation. Nearly 15 percent of all pump claims in 2004 did not have sufficient documentation to determine whether the claims met Medicare coverage criteria. In almost half of these cases, there was no documentation in the medical record indicating that the pump was ordered or used. In other cases, the type of wound for which the pump was prescribed was not clearly indicated, or the size of the wound was

relatively small and the reviewers could not determine whether the pump was medically necessary.

For continued coverage, the majority of the claims that were insufficiently documented did not include any documentation of changes in the dimensions or characteristics of the wound or did not show that the wound was healing. Some of the records also did not indicate that a licensed medical professional was directly assessing the wound being treated with the pump or supervising or directly performing the dressing changes on a regular basis, as required.

Undocumented. About 6 percent of all pump claims in 2004 were undocumented. For these claims, neither the physician who ordered the pump nor the HHA nor the SNF that we identified submitted any documentation that corresponded to the time period of our review. In one instance, the physician acknowledged that the patient was never placed on the pump. In another instance, the physician stated that she did not have any records to substantiate the order.

Medically unnecessary. Reviewers determined that 3 percent of all pump claims in 2004 were not medically necessary. In one instance, documentation showed that there was a fistula to an organ or body cavity within the vicinity of the wound. According to the LMRP, coverage must be denied if such a condition exists.[22] In another instance, the claim was not medically necessary because the pump was used on a patient who had unna boots placed on the wound. An unna boot is a dressing that envelops the wound like a cast and cannot be used in conjunction with the pump.

For continued coverage, nearly all of the claims that were not medically necessary did not have a measurable degree of healing over the past month. In a few of these cases, the wound size actually increased.

[22] "LMRP for Negative Pressure Wound Therapy Pumps (L5008)," § B(2).

Virtually all pump claims met supplier documentation requirements

Medicare requires suppliers to keep on file a number of documents, including the physician order and proof of delivery, for each claim. It also requires that the supplier possess the physician order before delivering the pump.[23] About 2 percent of claims in 2004 did not meet these requirements. In each case, the supplier either did not provide proof of delivery or did not have a record of providing the pump to the patient on the date of service in our sample.

For all other claims, the supplier had the appropriate documentation, i.e., a signed and dated order by the treating physician and proof of delivery. In addition, when we compared the dates on the physician order and the proof of delivery, we found that the pump had been delivered on or after the date on the physician order in every case, as required. The supplier also had the additional required documentation to justify continued coverage for all of the claims for the fifth and successive months.

For 44 percent of the claims, the information on the supplier-prepared statement was not fully supported by the medical record

Supplier-prepared statements are completed by the physician or treating clinician and contain clinical information relating to the initial order or continued coverage of the pump. According to the "Medicare Program Integrity Manual," there must be information in the medical record to substantiate the information provided on a supplier-prepared statement.[24] The supplier provided prepared statements for 99 percent of the claims in our sample. For the claims that had both a supplier-prepared statement and a medical record, the reviewers compared the information on the statement to the information in the medical record.[25]

For 44 percent of these claims, the reviewers determined that the information on the supplier-prepared statement was not fully supported by the medical record. The supplier-prepared statements commonly had

[23] CMS, "Medicare Program Integrity Manual," chapter 5, section 1.1, Rev. 3, November 22, 2000.

[24] Ibid.

[25] The reviewers compared the information on the clinical form and on the wound progress form to the information in the medical record. The reviewers conducted this analysis for the claims that had supplier-prepared statements and medical records. This analysis included a total of 348 claims.

wound measurements that were not noted in the medical record. Other types of information that were not supported by the medical record included the type of wound, other therapies tried prior to the pump order, an indication that the pump was being used, or an indication that regular assessments of the wound were being conducted.

Additionally, for 7 percent of the claims that had a supplier-prepared statement, the reviewers found discrepancies between the information on the supplier-prepared statement and the medical record. In these instances, the number, type, location, and/or existing measurements of the wound in the medical record did not match the information on the supplier-prepared statement. For example, in one instance, the supplier-prepared statement indicated that the wound was a pressure ulcer but the medical record indicated that the wound was a nonhealing, infected, postamputation wound. In another example, the reviewer noted that the measurements recorded in the medical record were "much smaller" than the measurements recorded in the supplier-prepared statement, despite the fact that the measurements were taken 3 days apart.

DMERCs had some safeguards in place to prevent improper payments

Based on our interviews with the medical director and other officials at each of the DMERCs, we found that all four DMERCs had some safeguards in place to prevent or recoup improper payments for pump claims. All of the DMERCs had automated computer edits to flag issues for possible review, such as an edit for the KX modifier, which the supplier adds to the claim if all of the criteria in the LMRP are met.[26] Staff at the DMERCs also reported having other edits in place that were more general in nature. These edits included checks to determine whether the claim included a diagnosis code, whether the beneficiary was covered by Medicare, and where the service or item was provided.

Additionally, staff at all four DMERCs reported conducting medical reviews of pump claims, although their approaches differed. In the past 5 years, one DMERC conducted postpayment reviews of pump claims and another conducted both postpayment and prepayment reviews. The remaining two DMERCs conducted prepayment reviews, but the

[26] If the criteria are not met, the supplier must include additional documentation with the claim to justify coverage. Claims that do not have the KX modifier are automatically flagged for possible review.

reviews covered only claims for the fifth and successive months of pump use. Also, the number of pump claims each DMERC reviewed in 2004 varied. One DMERC reviewed 7,900 pump claims, while another DMERC did not review any claims during this time period.

To conduct these medical reviews, all four DMERCs requested the documentation from the supplier. Three of the DMERCs relied on the supplier to collect the medical records from the providers, and they based their reviews on these records. The fourth DMERC reviewed only the supplier-prepared statement for each claim. All four DMERCs commented that they relied on a combination of the coverage criteria and clinical judgment to determine whether the pump was medically necessary and met Medicare coverage criteria. They also noted that their reviews or claim denials occasionally resulted in education to the supplier with the expectation that the supplier would then, in turn, educate physicians when needed.

RECOMMENDATIONS

We found that based on a review of medical records, 24 percent of all pump claims in 2004 did not meet Medicare coverage criteria, resulting in an estimated $21 million in improper payments. We also found that 44 percent of the claims had information on the supplier-prepared statement that was not fully supported by the medical record.

Based on the results of our review, we recommend that CMS, through its Provider Communications Group and DME contractors:

Ensure that claims for the pump meet Medicare coverage criteria and are paid appropriately

CMS should conduct the following activities to address this recommendation:

- CMS should instruct PSCs to conduct additional medical reviews of pump claims and to focus on claims for the initial month as well as for subsequent months.
- CMS should instruct PSCs to review the medical record and not only the supplier-prepared statements to determine whether a claim meets Medicare coverage criteria.
- CMS, through its Provider Communications Group, should work with MACs to educate suppliers and providers about the criteria required for Medicare coverage of the pump. Education should be focused on the information that needs to be documented in the medical record.

CMS should also consider the following options to address this recommendation:

- Establish advance coverage determinations of pump claims from suppliers that have a high number of claims that have been denied or a pattern of overutilization, pursuant to § 1834(a)(15) of the Act.
- In a manner similar to the requirements for power mobility devices, (1) require a face-to-face examination of the patient by the physician before writing the order for the pump and at regular intervals for continued coverage and (2) require the supplier to obtain a written report of these examinations and other relevant documentation from the physician that clearly supports the medical necessity for the pump.

- As an alternative to the previous suggestion, require the supplier to obtain from the physician or treating clinician pertinent parts of the patient's medical record that clearly support the medical necessity of the pump. Such documentation could include a digital picture of the wound that includes a scale to document the size of the wound.
- Further strengthen the coverage criteria for the pump to ensure that the pump is provided only when it is medically necessary.
- Increase prepayment reviews of pump claims.

In addition to these recommendations, we forwarded information on the insufficiently documented, undocumented, and medically unnecessary claims identified in our sample to CMS for appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurs with our three recommendations to ensure that claims for the pump meet Medicare coverage criteria and are paid appropriately. CMS states that it will work with PSCs to prioritize medical reviews of pump claims with other high-risk services. It will also require that medical reviews of pump claims be based on the entire medical record. Finally, it will direct its contractors to develop an education article based on our findings.

CMS does not concur with the five additional options we recommended for consideration. Specifically, it notes that advance coverage determinations and face-to-face examinations may impose significant delays or difficulties in the provision of the pump, which is often prescribed in urgent situations. It believes that the alternative option we proposed, requiring suppliers to obtain medical records to support medical necessity, is sufficiently addressed by current requirements. It also believes that our findings do not support changes to the coverage criteria and increased prepayment reviews.

We understand CMS's concerns that implementing advance coverage determinations or face-to-face examinations may impose significant delays in the provision of the pump. However, we continue to recommend that CMS consider the third option—requiring the supplier to obtain pertinent parts of the patient's medical record prior to submitting a claim for the pump—as an important mechanism to curb inappropriate payments. CMS notes that suppliers are already

required to submit information from the patient's medical record to support the medical necessity of the item. We note that section 5.7 of the "Program Integrity Manual" specifically states that the documentation in the patient's medical record does not have to be routinely sent to the supplier or the DMERC, and that the DMERC may request the information in selected cases. Based on our review, we found that in practice, the supplier typically asks the ordering physician to complete a supplier-prepared statement and that for 44 percent of the claims, the supplier-prepared statement was not supported by the medical record. Therefore, requiring that suppliers obtain pertinent parts of the patient's medical record may help to ensure that suppliers are submitting appropriate claims. Appendix D provides the full text of CMS's comments.

APPENDIX ~ A

LMRP for Negative Pressure Wound Therapy (NPWT) Pumps

This Appendix contains the coverage and payment rules, the supplier documentation requirements, and the HCPCS codes effective in 2004 as they appeared in LMRPs issued by all four DMERC regions.[27] We have included only sections of these LMRPs that are relevant to our study. Full copies of LMRPs from all DMERC regions can be found at http://coverage.cms.fu.com/mcd%5Farchive/search.asp.

LMRP Information

A "Local Coverage Determination" (LCD), as established by Section 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist only of "reasonable and necessary" information, while LMRPs may also contain category or statutory provisions.

The final rule establishing LCDs was published November 11, 2003. Effective December 7, 2003, CMS's contractors will begin issuing LCDs instead of LMRPs. Over the next 2 years (until December 31, 2005) contractors will convert all existing LMRPs into LCDs and articles. Until the conversion is complete, for purposes of a 522 challenge, the term LCD will refer to both 1.) Reasonable and necessary provisions of an LMRP and, 2.) an LCD that contains only reasonable and necessary language. Any non-reasonable and necessary language a contractor wishes to communicate to providers must be done through an article.

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

[27] The HCPCS codes contained in these LMRPs were revised, effective April 1, 2004. This Appendix contains the permanent codes that became effective on that date. Our sample included claims from 2004 associated with the HCPCS codes in effect both before and after the LMRP revision.

For an item addressed in this policy to be covered by Medicare, a written signed and dated order must be received by the supplier prior to delivery of the item. If the supplier delivers the item prior to receipt of a written order, it will be denied as noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

EQUIPMENT:

INITIAL COVERAGE:

An NPWT pump and supplies are covered when either criterion A or B is met:

A) Ulcers and Wounds in the Home Setting:

The patient has a chronic Stage III or IV pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

1) For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:

a) Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional, and

b) Application of dressings to maintain a moist wound environment, and

c) Debridement of necrotic tissue if present, and

d) Evaluation of and provision for adequate nutritional status.

2) For Stage III or IV pressure ulcers:

a) The patient has been appropriately turned and positioned, and

b) The patient has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see DMERC medical policy on support surfaces), (a group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis) and

c) The patient's moisture and incontinence have been appropriately managed.

3) For neuropathic (for example, diabetic) ulcers:

a) The patient has been on a comprehensive diabetic management program, and

b) Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.

4) For venous insufficiency ulcers:

a) Compression bandages and/or garments have been consistently applied, and

b) Leg elevation and ambulation have been encouraged.

B) Ulcers and Wounds Encountered in an Inpatient Setting:

1) An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating physician, the best available treatment option.

2) The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments).

In either situation B-1 or B-2, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting.

If criterion A or B above is not met, the NPWT pump and supplies will be denied as not medically necessary.

NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds on a patient. Therefore, more than one E2402 billed per patient for the same time period will be denied as not medically necessary.

OTHER EXCLUSIONS FROM COVERAGE:

An NPWT pump and supplies will be denied at any time as not medically necessary if one or more of the following are present:

- the presence in the wound of necrotic tissue with eschar, if debridement is not attempted;

- untreated osteomyelitis within the vicinity of the wound;

- cancer present in the wound;

- the presence of a fistula to an organ or body cavity within the vicinity of the wound.

NPWT pumps and their supplies, which have not been specifically designated as being qualified for use of HCPCS codes E2402, A6550 and A6551 for billing to the DMERC via written instructions from the SADMERC, will be denied as not medically necessary.

CONTINUED COVERAGE:

C) For wounds and ulcers described under A or B above, once placed on an NPWT pump and supplies, in order for coverage to continue a licensed medical professional must do the following:

1) On a regular basis,

a) directly assess the wound(s) being treated with the NPWT pump, and

b) supervise or directly perform the NPWT dressing changes, and

2) On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If criteria C-1 and C-2 are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not medically necessary.

WHEN COVERAGE ENDS:

D) For wounds and ulcers described under A or B above, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:

1) Criteria C1-C2 cease to occur,

2) In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,

3) Any measurable degree of wound healing has failed to occur over the prior month. There must be documented in the patient's medical records quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented, over a specified time interval. The recorded wound measurements must be consistently and regularly updated and must have demonstrated progressive wound healing from month to month,

4) 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound. Coverage beyond 4 months will be given individual consideration based upon required additional documentation,

5) Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

SUPPLIES:

- Coverage is provided up to a maximum of 15 dressing kits (A6550) per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.

- Coverage is provided up to a maximum of 10 canister sets (A6551) per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). For high volume exudative wounds, a stationary pump with the largest capacity canister must be used. Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) will be denied as not medically necessary.

The medical necessity for use of a greater quantity of supplies than the amounts listed must be clearly documented in the patient's medical record and may be requested by the DMERC. If this documentation is not present, excess quantities will be denied for lack of medical necessity.

HCPCS MODIFIER:

EY - No physician or other health care provider order for this item or service
KX - Specific required documentation on file.

EQUIPMENT

E2402	NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE

SUPPLIES

A6550	DRESSING SET FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE, EACH
A6551	CANISTER SET FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE, EACH

ICD-9 Codes that Support Medical Necessity

Not specified.

Diagnoses that Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity

Not specified

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Not specified.

Reasons for Denials

Items listed in this policy will be denied as not medically necessary when provided for conditions other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section unless it specifically states in that section that they will be denied as noncovered.

Non-covered ICD-9 Codes

Non-covered Diagnoses

Not specified.

Coding Guidelines

EQUIPMENT:

Negative pressure wound therapy (NPWT) is the controlled application of subatmospheric pressure to a wound using an electrical pump (described in the definition of HCPCS code E2402) to intermittently or continuously convey subatmospheric pressure through connecting tubing to a specialized wound dressing (described in the descriptor of HCPCS code A6550) which includes a resilient, open-cell foam surface dressing, sealed with an occlusive dressing that is meant to contain the subatmospheric pressure at the wound site and thereby promote wound healing. Drainage from the wound is collected in a canister (described in the definition of HCPCS code A6551).

HCPCS code E2402 describes a stationary or portable NPWT electrical pump which provides controlled subatmospheric pressure that is designed for use with NPWT dressings, (A6550) to promote wound healing. Such an NPWT pump is capable of being selectively switched between continuous and intermittent modes of operation and is controllable to adjust the degree of subatmospheric pressure conveyed to the wound in a range from 25 to greater than or equal to 200 mm Hg subatmospheric pressure. The pump is capable of sounding an audible alarm when desired pressures are not being achieved (that is, where there is a leak in the dressing seal) and when its wound drainage canister (A6551) is full. The pump is designed to fill the canister to full capacity.

SUPPLIES:

HCPCS code A6550 describes a dressing set which is used in conjunction with a stationary or portable NPWT pump (E2402), and contains all necessary components, including but not limited to a resilient, open-cell foam surface dressing, drainage tubing, and an occlusive dressing which creates a seal around the wound site for maintaining subatmospheric pressure at the wound.

HCPCS code A6551 describes a canister set which is used in conjunction with a stationary or portable NPWT pump (E2402) and contains all necessary components, including but not limited to a container, to collect wound exudate. Canisters may be various sizes to accommodate stationary or portable NPWT pumps.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

General Information

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. section 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available to the DMERC upon request. Items delivered before a signed written order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

Documentation of the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the patient's medical record and be available for review if requested by the DMERC. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).

Documentation of wound evaluation and treatment, recorded in the patient's medical record, must indicate regular evaluation and treatment of the patient's wounds, as detailed in the Coverage and Payment Section. Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly. The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the patient's medical record, in order to determine whether the equipment and supplies continue to qualify for Medicare coverage. (The supplier need not view the medical records in order to bill for continued use of NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the supplier. However, the patient's medical records may be requested by the DMERC in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement.)

When billing for NPWT, an ICD-9-CM diagnosis code (specific to the fifth digit or narrative diagnosis), describing the wound being treated by NPWT, must be included on each order and on each claim for the equipment and related supplies.

Suppliers must add a KX modifier to a code only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met. If the coverage criteria for the KX modifier are not met, the supplier may submit additional documentation with the claim to justify coverage, but the KX modifier must not be used.

A KX modifier must not be used with an NPWT pump and supplies for wounds (described under A or B in the Coverage and Payment Rules Section) in the fifth and successive months, but additional documentation may be submitted for individual consideration. The claim must include a statement from the treating physician describing the initial condition of the wound including measurements, efforts to address all aspects of wound care (listed in A-1 through A-4). Each subsequent monthly claim must also include updated wound measurements and what changes in wound therapy are being applied to effect wound healing.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, each claim must include documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered in the narrative field of an electronic claim. Additionally, there must be clear documentation in the patient's medical records corroborating the medical necessity of this amount.

Refer to the Supplier Manual for more information on documentation requirements.

Other Comments

A licensed health care professional, for the purposes of this policy, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.

Lack of improvement of a wound, as used within this policy, is defined as a lack of progress in quantitative measurements of wound characteristics including wound length and width (surface area), or depth measured serially and documented, over a specified time interval. Wound healing is defined as improvement occurring in either surface area or depth of the wound.

A P P E N D I X ~ A

The staging of pressure ulcers used in this policy is as follows:

Stage I - Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.

Stage II - Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.

Stage III - Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage IV - Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

APPENDIX ~ B

Detailed Methodology

Sample Selection

We selected a simple random sample of 400 claim line items for the pump from CMS's National Claims History file.[28] First, we identified the two Healthcare Common Procedure Coding System (HCPCS) codes that suppliers used in 2004 to bill for the pump—K0538 and E2402.[29] We then identified all of the allowed claims associated with these HCPCS codes that had a service date in 2004.[30] The universe consisted of 53,507 claims that represented $89,999,824 in allowed payments.

From our sample of 400 claims, we excluded a claim because of an ongoing investigation by the Office of Inspector General. Fifty-eight percent of the remaining 399 claims were for the initial month, and 42 percent were for subsequent months.

Medical Record Request

Given the wide array of types of medical care that beneficiaries may require when using the pump, we compiled as comprehensive a medical record as possible for each claim. We requested the medical records for the claims in our sample from the physician who prescribed the pump and any HHAs and/or SNFs that billed Medicare for services provided to the beneficiary on the sampled claim.

We identified the physician who ordered the pump by using the Unique Physician Identification Number (UPIN) listed on each claim. We then obtained the physician's contact information from CMS's UPIN Validation File. For the claims that did not have a valid UPIN, we obtained the physician contact information from the documentation provided by the supplier. We requested the medical record from each physician beginning from the initial evaluation of the wound(s) for which the pump was ordered through 30 days after the service date on the claim. We specifically asked the physician to include any documentation from other providers related to the treatment of the relevant wound(s).

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[28] Multiple line items for individual services and procedures may be billed within a single claim. For this report, we refer to claim line items as claims.

[29] In 2004, the temporary HCPCS code for the pump, K0538, was in effect from January 1 to March 31. The permanent HCPCS code, E2402, was in effect from April 1 to December 31.

[30] We did not include claims from outside the 50 States and the District of Columbia.

We identified any HHAs and/or SNFs that billed Medicare for services provided to the beneficiary on the sampled claim in the 3 months prior to the service date. From each HHA and SNF, we requested the medical record from 2 months prior to the service date on the claim through 30 days after the service date. We requested that each provider submit all documentation of the evaluation and management of the wound(s) for which the pump was ordered.[31]

We used a contractor to collect the medical records. For the claims that had out-of-date or incomplete contact information for the physician, HHA, and/or SNF, the contractor searched online phonebooks, State licensing boards, physician association directories, and called prior medical practices to obtain updated contact information. Once an address was verified, the contractor made at least three attempts to obtain the medical record from each provider. On the last attempt, the contractor sent a certified letter or called the provider to verify that they received the request.

Response to OIG Medical Record Request

We included 378 of 399 claims in our analysis, for a response rate of 95 percent. We received useable medical records for 356 claims. For another 22 claims, despite numerous attempts, neither the physician who ordered the pump nor the HHA or SNF that we contacted submitted any documentation that corresponded to the time period of our review. In our analysis, we considered these claims to be undocumented.

We did not include the remaining 21 claims in our analysis. For 11 of these claims, we were not able to locate a current address for either the physician, HHA, or SNF. For an additional two claims, we received the records after the review had been conducted. For another eight claims, we determined that the medical record was missing some specific information that may have been found in another provider's medical record, which we were unable to obtain in our study timeframe.

Medical Record Review

We used a contractor to conduct the medical review. The reviewers included three registered nurses, each of whom had at least 5 years of wound care experience. The reviewers used a standardized instrument

[31] For the SNF records, we specifically requested all physician, nursing, nurse's aide, physical therapist, and nutrition notes, as well as any physician orders.

to review the medical record and determine whether each sampled claim met Medicare coverage criteria. The review instrument included questions based on the criteria in the LMRP. For example, it asked about the characteristics of the wound for which the pump was prescribed and any existing conditions that are specifically excluded from coverage. It also included specific questions depending upon the type of wound and depending upon whether the claim was for initial or continued coverage. The reviewers did not consider the supplier-prepared statements submitted by the supplier in making their determinations.

Test review. To test our instrument and to further train our reviewers, the reviewers conducted a preliminary medical review of 20 claims that we randomly selected from the universe of all claims in 2004. This sample was separate from the sample of 400 used for the actual review.[32]

Final sample review. Using the final instrument, the contractor reviewed the medical records for the sampled claims. The reviewers entered the information directly into a computer-based system that included automated skip patterns and quality control checks.

Analysis of data. We analyzed the results of the medical review using Statistical Analysis System software and identified the proportion of claims that were medically unnecessary, insufficiently documented, and undocumented. As part of our analysis, we looked to see whether there were any statistically significant differences in the error rates between initial claims and continued claims.

We also identified the supplies associated with the inappropriate pump claims that were billed within 30 days after the service date of the pump claim. We reasoned that if the pump claim was inappropriate, any supplies billed during this time period were also inappropriate. We calculated the total dollars paid in error for the pump claims and the associated supply claims and projected this amount to the universe of all pump claims and associated supply claims in 2004.

Review of Supplier Documentation

We conducted a separate review of the documentation provided by the supplier. To accomplish this, we requested all of the documentation

[32] All claims in 2004 were given a chance for selection in both samples. There was no overlap of claims between the samples.

from the supplier related to each of the sampled claims. The supplier provided documentation for 396 of the 399 claims in our sample. The documentation included the forms and supplier-prepared statements described in the "Background" section.

We reviewed the documentation to determine whether it met Medicare supplier documentation requirements. Specifically, we determined whether there was a signed and dated physician order and proof of delivery. We also determined whether there was documentation of wound healing and of continued need for coverage for claims that extended beyond 4 months. The contractor then reviewed the supplier documentation, i.e., the supplier-prepared statements, to determine whether the information on these statements was supported by the medical record.

Structured Interviews with DMERC Staff

We conducted structured telephone interviews with staff at the four DMERCs and the SADMERC. We spoke with the medical director and other staff at three of the DMERCs. At the fourth DMERC, we spoke with the medical review manager and other staff. At the SADMERC, we spoke with the medical director and other staff. Our questions focused on the types of program safeguards each DMERC had in place to prevent and recoup improper payments for pump claims. We also asked about any analysis conducted on the pump claims and education efforts provided to suppliers or physicians. Finally, we reviewed supplemental documentation provided by DMERCs and the SADMERC.

APPENDIX ~ C

Confidence Intervals for Selected Estimates

Estimate Description	n	Point Estimate	95-Percent Confidence Interval
Percentage of all pump claims that did not meet Medicare coverage criteria	378	24.1%	19.8 – 28.4 %
Percentage of insufficiently documented claims	378	14.8%	11.2 – 18.4 %
Percentage of undocumented claims	378	5.8%	3.5 – 8.2 %
Percentage of medically unnecessary claims	378	3.4%	1.6 – 5.3 %
Percentage of claims that did not meet Medicare supplier documentation requirements	399	1.5%	0.3 – 2.7 %
Percentage of claims in which the information on the supplier-prepared statement was not fully supported by the medical record	348*	44.3%	39.0 – 49.5 %

Source: Office of Inspector General medical review results, 2006.

*This is the total number of claims that had both supplier-prepared statements and medical records.

Estimate Description	n	Point Estimate	95-Percent Confidence Interval
Amount allowed for all pump claims that did not meet Medicare coverage criteria	378	$20,721,994	$17,003,520 – $24,440,469
Amount allowed for supplies associated with pump claims that did not meet Medicare coverage criteria	378	$5,937,137	$4,475,555 – $7,398,719
Amount allowed for insufficiently documented claims	378	$12,800,567	$9,701,155 – $15,899,978
Amount allowed for undocumented claims	378	$4,993,943	$2,963,783 – $7,024,104
Amount allowed for medically unnecessary claims	378	$2,927,484	$1,358,427 – $4,496,541

Source: Office of Inspector General medical review results, 2006.

APPENDIX ~ D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAY 11 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Payments for Negative Pressure Wound Therapy Pumps in 2004" (OEI-02-05-00370)

Thank you for the opportunity to review the OIG draft audit report on negative pressure wound therapy (NPWT) pumps. NPWT pumps are a portable or stationary device used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. The NPWT pump applies controlled pressure to the wound and assists in removing fluid, increasing blood flow to the site, and stimulating the growth of tissue. Wound care is often managed by clinicians, such as home care nurses or physical therapists. NPWT pumps are often prescribed in acute or urgent situations, such as chronic pressure ulcers or complications from a surgically-created wound.

The Centers for Medicare & Medicaid Services (CMS) recently issued a final rule to implement a new competitive bidding program in Medicare that will reduce beneficiary out-of-pocket costs, improve the accuracy of Medicare payments, and ensure beneficiary access to high quality medical equipment and supplies. The new Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program will strengthen Medicare's efforts to protect seniors and people with disabilities from fraud and high out-of-pocket costs. Competition under the new program will begin in 10 major metropolitan statistical areas this year, fundamentally changing the way CMS determines payment amounts for subject items by using bids submitted by DMEPOS suppliers to establish payment amounts. Suppliers that submit the lowest bids and that meet strict new quality standards and accreditation requirements, as well as financial and other requirements, will be awarded contracts to furnish bid products to Medicare beneficiaries. NPWT devices and related supplies and accessories comprise one of the first 10 product categories included in the first round of bidding. These product categories were selected due to their high cost and volume or greatest savings potential.

We appreciate OIG's efforts to determine which claims for NPWT pumps met Medicare coverage criteria and supplier documentation requirements in 2004. In this report, OIG found

that CMS needed to implement additional measures to ensure that claims for NPWT pumps meet Medicare coverage criteria and are paid appropriately. Our response to the audit recommendation follows.

OIG Recommendation

The OIG recommended that CMS ensure that claims for the pump meet Medicare coverage criteria and are paid appropriately. To this end, OIG offered the following suggestions to implement this recommendation:

- CMS should instruct program safeguard contractors (PSCs) to conduct additional medical reviews of pump claims and to focus on claims for the initial month as well as for subsequent months;
- CMS should instruct PSCs to review the medical record and not only the supplier-prepared statements to determine whether a claim meets Medicare coverage criteria;
- CMS, through its Provider Communication Group, should work with Medicare administrative contractors (MACs) to educate suppliers and providers about the criteria required for Medicare coverage of the pump;
- CMS should establish advance coverage determinations of pump claims from suppliers that have a high number of claims that have been denied or a pattern of overutilization, pursuant to Section 1834(a)(15) of the Social Security Act;
- CMS should, in a manner similar to the requirements for power mobility devices, (a) require a face-to-face examination of the patient by the physician before writing the order for the pump and at regular intervals for continued coverage and (b) require the supplier to obtain a written report of these examinations and other relevant documentation from the physician that clearly supports the medical necessity for the pump;
- CMS should, as an alternative to the previous suggestion, require the supplier to obtain from the physician or treating clinician pertinent parts of the patient's medical record that clearly support the medical necessity of the pump;
- CMS should further strengthen the coverage criteria for the pump to ensure that the pump is provided only when it is medically necessary; and
- CMS should increase prepayment reviews of pump claims.

CMS Response

- **CMS should instruct PSCs to conduct additional medical reviews of pump claims and to focus on claims for the initial month as well as for subsequent months.**

- **CMS should instruct PSCs to review the medical record and not only the supplier-prepared statements to determine whether a claim meets Medicare coverage criteria.**

The CMS agrees with these suggested activities by the OIG. Our contractors will be asked to prioritize this service with other high-risk services and, based on data analysis, focus their medical review resources on the highest risk services or providers. We will also require that medical review of NPWT pump claims be based on the entire medical record.

- **CMS, through its Provider Communication Group, should work with MACs to educate suppliers and providers about the criteria required for Medicare coverage of the pump.**

We concur. Following the release of this OIG report, the contractors will be directed to develop an education article on the OIG findings.

- **CMS should establish advance coverage determinations of pump claims from suppliers that have a high number of claims that have been denied or a pattern of overutilization, pursuant to Section 1834(a)(15) of the Social Security Act.**

We do not agree with the OIG on this suggestion. Currently, advance determination of Medicare coverage (ADMC) is a voluntary program, and beneficiaries and suppliers are not required to submit ADMC requests in order to submit claims for items. In addition, the ADMC process is lengthy and may impose significant delays in the provision of this item. Given that an NPWT pump is often prescribed in urgent situations, such a time delay could be problematic.

- **CMS should, in a manner similar to the requirements for power mobility devices, (a) require a face-to-face examination of the patient by the physician before writing the order for the pump and at regular intervals for continued coverage and (b) require the supplier to obtain a written report of these examinations and other relevant documentation from the physician that clearly supports the medical necessity for the pump.**

- **CMS should, as an alternative to the previous suggestion, require the supplier to obtain from the physician or treating clinician pertinent parts of the patient's medical record that clearly support the medical necessity of the pump.**

Under section 302(a)(2)(E)(ii) of the Medicare Modernization Act of 2003, CMS does have authority to, at its discretion, require face-to-face examinations as a condition for payment for covered DME items, but we have not implemented regulations or other guidance pursuant to this authority. CMS has chosen not to extend the face-to-face requirement to NPWT pumps, as NPWT pumps are often prescribed in acute or urgent situations and getting a homebound patient to see a physician for a formal face-to-face examination may delay provision of the item. Suppliers are already required to submit information from the patient's medical record to support the medical necessity for the item. CMS' current requirements allow medical records from these

health care professionals to be sufficient documentation of medical necessity. Requiring a face-to-face evaluation at regular intervals during continued use of the pump would pose additional difficulties.

The CMS does agree with the OIG's suggestion to broaden the scope of information that can be used as supporting documentation. As we mentioned earlier, following the release of this OIG report, we will develop educational materials on the OIG findings.

- **CMS should further strengthen the coverage criteria for the pump to ensure that the pump is provided only when it is medically necessary.**

- **CMS should increase prepayment reviews of pump claims.**

The OIG did not provide sufficient evidence in this report for CMS to address these suggestions. The findings of the OIG report indicate that there was insufficient documentation in the patient's medical record to verify that the Medicare coverage criteria had been met. However, the OIG did not clarify what additional Medicare coverage criteria should be considered. If the OIG submits this information to us, we will review this information and take the appropriate action.

Again, we thank OIG for its effort on this report. We look forward to working together with you in the future as we continue to prevent fraud, waste, and abuse in the Medicare program.

ACKNOWLEDGMENTS

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