CMS Outlines Medicare Part B Drug Demonstration Project

On April 13, 2004, the Centers for Medicare & Medicaid Services (CMS) released a general overview of the demonstration project that will cover self-administered Part B drugs for two years, as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).

Out of the total $500 million set aside for this demonstration project, CMS intends to appropriate $200 million specifically for anticancer medicines. This move is in response to the intent of MMA conferees who wanted to allocate 40 percent of the total project funds specifically to cancer patients.

Specific drugs that will be covered have not yet been determined; however, CMS has issued guidelines as to which drugs will be eligible. First, the drug must replace a drug that is currently administered by a physician; the oral drug may not be used together with a physician-administered drug. Second, the drug must be advantageous to the convenience of the patient, either in obtaining the drug or in its administration. Finally, the drug must equal or surpass the clinical effectiveness of a currently covered therapy. Therefore, drugs such as tamoxifen will not be covered, because they do not replace a currently covered medication. In addition, CMS has determined that because of the limited budget and limited number of participants allowed by the MMA, off-label drugs will *not* be covered.

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In order to expand the number of demonstration project participants, CMS has proposed two options that would separate participants into "pools." The first option would separate cancer drug participants from all others. Participants would first be selected for the cancer-specific pool until the appropriated $200 million was depleted. Then, participants would be selected for the other pool until either the remaining $300 million was used or the participant cap of 50,000 people was reached.

In the second scenario, the cancer participants would remain in a

Hospital Alert! New Codes, New Payments for Brand-Name Drugs

On Feb. 27, 2004, CMS increased payments for 32 brand-name drugs in the hospital outpatient department and created new HCPCS codes to distinguish brand-name drugs from generic drugs. Starting April 1, 2004, hospitals should use these new HCPCS codes when submitting claims for brand-name cancer drugs. (CMS calls these "multiple-source innovator drugs.") Hospitals can submit adjustment payments for services provided with brand-name drugs between January 1 and March 31, 2004.

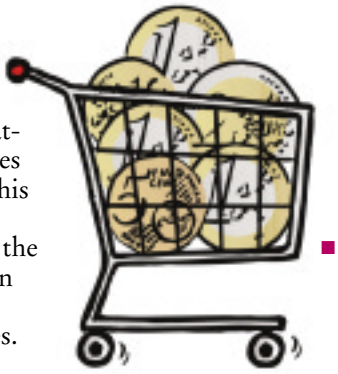
New codes and payments for selected brand-name cancer drugs:

- C9417 Blenoxane® (bleomycin sulfate injection)
  Payment: $130.56
  Copayment: $26.11
- C9426 FUDR (floxuridine injection)
  Payment: $97.92
  Copayment: $19.58
- C9427 Ifex® (ifosfamide injection)
  Payment: $106.04
  Copayment: $21.21
- C9429 Idamycin® (idarubicin HCl injection)
  Payment: $178.21
  Copayment: $35.64
- C9430 Lupron® (leuprolide acetate injection)
  Payment: $21.41
  Copayment: $4.28
- C9431 Taxol® (paclitaxel injection)
  Payment rate: $112.14
  Copayment rate: $22.43
- C9432 Mutamycin® (mitomycin injection)
  Payment: $45.70
  Copayment: $9.14

Generic multiple-source cancer drugs:

- J9040 bleomycin sulfate injection
  Payment: $88.32
  Copayment: $17.66
- J9200 floxuridine injection
  Payment: $66.24
  Copayment: $13.25
- J9208 ifosfamide injection
  Payment: $72.81
  Copayment: $14.56
- J9211 idarubicin HCl injection
  Payment: $178.21
  Copayment: $35.64
- J9218 leuprolide acetate injection
  Payment: $14.48
  Copayment: $2.90
- J9265 paclitaxel injection
  Payment: $79.04
  Copayment: $15.81
- J9280 mitomycin 5 mg injection
  Payment: $30.91
  Copayment: $6.18

For a list of all 32 drugs, go to ACCC's web site at *www.accc-cancer.org/images/cmschart.pdf*.



distinct pool, but the remaining participants would be separated into larger categories of covered diseases. This option would require negotiation as to how the remaining $300 million will be distributed among these categories.

CMS has requested comments regarding these two options, and welcomes alternative proposals. CMS held a special open door public meeting regarding this demonstration project on April 23, 2004. For more information, visit CMS at *http://www.cms.hhs.gov/opendoor/*.

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Physician Practices Take Note: Part B Drug Payments Updated

CMS released a one-time notification on March 15, 2004, that updated the reimbursement rates for nine drugs under Medicare Part B that are not paid on a cost or prospective payment basis. The new payment rates for the listed drugs are effective from April 1, 2004, through Dec. 31, 2004, and this update takes authority over any other information released for these drugs during that time period.

Here's a look at the updated drug payments that may affect physician practices:

- J2353 octreotide acetate injection will be paid at 92 percent of AWP with a payment limit of $77.14.
- J9045 carboplatin injection will be paid at 88 percent of AWP with a payment limit of $137.54.
- J9201 gemcitabine HCl will be paid at 87 percent of AWP with a payment limit of $111.33.
- J9206 irinotecan injection will be paid at 85 percent of AWP with a payment limit of $130.24.

Hospitals! Get Special Payments Under Medicare for Additional Drugs and Services

Effective April 1, hospitals will receive special payments, known as pass-through payments, for an additional drug and three services related to cancer care under Medicare rules that allow such payments for some outpatient care.

CMS said the special drug payment is for rasburicase, an injectable treatment for high uric acid levels that may result from certain cancer treatments.

The three outpatient services to receive payment as new technologies are a procedure using a laser device that vaporizes the prostate and controls bleeding before and after the procedure; a concurrent or immediate placement of a balloon catheter in the breast for interstitial radiation therapy following a partial mastectomy; and delayed placement of a balloon catheter into the breast for interstitial radiation therapy following a partial mastectomy.

The payments are made under the hospital outpatient prospective payment system (OPPS), which offers temporary extra money until there are sufficient cost data available from outpatient services to develop an appropriate price. In a statement, CMS said the payments will ensure that Medicare beneficiaries have prompt access to improvements in outpatient care.

The new payment rates were included in a quarterly update to the OPPS. Under this system, hospitals are paid for outpatient services based on ambulatory payment classifications (APCs) that are clinically similar and require similar resources.

The notification of the April update is located at *http://www.cms.hhs.gov/manuals/pm_trans/R132CP.pdf*.

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Whoops, CMS Corrects Payment Mistake

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CMS adjusted the payment rates for 28 drugs, biologicals, and radiopharmaceuticals on Feb. 27, 2004. Originally published in the Jan. 6, 2004 *Federal Register*, these rates were found to be incorrect because they were based on inaccurate average wholesale price (AWP) data. Therefore, all payments made for the first quarter of 2004 have been inaccurate. CMS has instructed its fiscal intermediaries to correct this information in their databases and to adjust payments that were submitted between Jan. 1, 2004, and March 31, 2004, after the new rates are implemented on April 1, 2004.

Here are the corrected drug payments that may affect cancer programs:

- J1563 immune globulin, 1 g.
  IFC payment: $37.95
  Corrected payment: $72.60
  Corrected copayment: $14.52
- J1564 immune globulin, 10 mg.
  IFC payment: $0.41
  Corrected payment: $0.79
  Corrected copayment: $0.16
- J1745 infliximab injection
  IFC payment: $31.81
  Corrected payment: $60.86
  Corrected copayment: $12.17
- Q0166 granisetron HCl, 1 mg. oral
  IFC payment: $171.78
  Corrected payment: $41.40
  Corrected copayment: $8.28
- Q0180 dolasetron mesylate oral
  IFC payment: $152.38
  Corrected payment: 67.09
  Corrected copayment: $13.42

For a list of the 23 other drugs, go to ACCC's web site at *www.accc-cancer.org*.

ACCC Works to Speed Up CMS' Payment Policy

ACCC and the APC Advisory Panel have requested that CMS change the way it pays claims for drugs newly approved by the Food and Drug Administration (FDA). ACCC's concern is that CMS' slow payment policy for innovative new drugs that do not have a HCPCS code is needlessly denying patients access to the breakthrough therapies that could save their lives. An entire new class of chemotherapeutic agents may wait on the shelf while a slow and cumbersome paperwork hurdle results in detrimental delays in Medicare beneficiaries' access to care.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that new drugs for which a HCPCS code has not been assigned be reimbursed at 95 percent of their average wholesale price (AWP). CMS, citing operational issues, has failed to implement this requirement. For patients with cancer, delay in receiving these drugs could mean the difference between life and death. Waiting for a few months while CMS deals with the bureaucracy of claims submission is simply not a possibility.

ACCC and other organizations have offered comments and testimony in the past regarding precisely how CMS could pay for new drugs immediately upon their FDA approval. ACCC believes that the best option is for CMS to add several new HCPCS codes to the system and then assign new drugs to these codes at their FDA approval. CMS could announce the code assignment on its web site within a few days of the FDA approval, and hospitals could begin using the code almost immediately.

NCCN Updates Guidelines for Non-Small Cell Lung Cancer

The National Comprehensive Cancer Network (NCCN) announced on March 8 a major update of the NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines. Most significantly, the recently approved targeted therapy gefitinib (Iressa®, AstraZeneca Pharmaceuticals LP) is now recommended as third-line therapy and as second-line only if the platinum/docetaxel combination was used as first-line therapy.

The NCCN's Non-Small Cell Lung Cancer guidelines panel has also added more detail to its recommendations for administration of chemotherapy to patients with this disease, including patient selection criteria and definition of first-, second-, and third-line agents and combinations.

Chemotherapeutic agents are specified as two-agent regimens for first-line therapy, two-agent regimens or single agents for second-line therapy, and one single agent for third-line therapy. Agents used in first- and second-line therapy are:

- cisplatin (Platinol®, Bristol-Myers Squibb Company)
- carboplatin (Paraplatin®, Bristol-Myers Squibb Company)
- paclitaxel (Taxol®, Bristol-Myers Squibb Company)
- docetaxel (Taxotere®, Aventis Pharmaceuticals Inc.)
- vinorelbine (Navelbine®, GlaxoSmithKline)
- gemcitabine (Gemzar®, Eli Lilly and Company)
- etoposide (Toposar™, Pfizer, Inc.; VePesid®, Bristol-Myers Squibb Company)
- etoposide phosphate (Etopophos®, Bristol-Myers Squibb Company)
- irinotecan (Camptosar®, Pfizer, Inc.)
- vinblastine (Velban®, Eli Lilly and Company)
- mitomycin (Mutamycin®, Bristol-Myers Squibb Company)
- ifosfamide (Ifex®, Bristol-Myers Squibb Company).

NCCN Clinical Practice Guidelines can be found online at *www.nccn.org*.

US Oncology to Merge, Become Privately Held

US Oncology, Inc., Houston, Tex., announced on March 22 that the company has signed an agreement to merge with Oiler

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Acquisition Corp., an affiliate of Welsh, Carson, Anderson & Stowe IX, L.P., one of the largest private equity firms in the U.S., which owns approximately 14.5 percent of US Oncology's common stock, the trade journal *Modern Healthcare* reports.

Upon completion of the transaction, which is valued at approximately $1.7 billion, including consideration for outstanding stock options and the assumption of certain debt obligations, US Oncology will become a privately held company. Switching from a publicly owned company to a privately owned company may be a good financial move for the company whose stock value often fluctuated depending on what was happening with Medicare. It is believed that the change to a privately held company will help protect US Oncology from the volatility of the reimbursement system. A special committee composed of independent directors unanimously recommended the transaction.

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Federal Panel to Study Drug Imports from Canada

As required under the MMA, the Bush administration announced plans to conduct a year-long study of how prescription drugs might be safely imported from Canada. In enacting the MMA, Congress instructed the administration to study whether drugs could be safely imported if the government hired additional inspectors, if all shipments were routed through specific ports, and if the products carried tiny electronic tags so they could be traced through the supply chain.

PHOTOGRAPHS/PICTUREQUEST.COM

The study is driven, in part, by a commonly held belief that the United States pays more for drugs than other industrialized countries. For example, a 2000 U.S. House of Representatives report that analyzed five brand-name prescription drugs that are commonly prescribed to treat breast cancer found the "average price for the five drugs to be 133 percent higher than the average price in Canada, the United Kingdom, France, and Italy."

CMS Under New Leadership

On March 12, the Senate approved President Bush's nominee, Mark McClellan, to head the Centers for Medicare & Medicaid Services (CMS). The agency oversees the Medicare and Medicaid programs, including the implementation of the MMA. McClellan succeeds Thomas A. Scully, who left the position late in 2003.

As head of CMS, McClellan will oversee the dramatic changes to the Medicare program enacted by Congress last year, including the new prescription drug program.

The Bush administration said the program would cost $400 billion over 10 years when it pushed for congressional passage. New budgets, however, project that the cost could be closer to $530 billion.

Additionally, healthcare executive Herb B. Kuhn has been named the new director of the Center for Medicare Management at CMS. Kuhn replaces Thomas L. Grissom, who left CMS in December 2003.

Five Cancer Drugs Among the Most Counterfeited

In February 2004, the National Association of Boards of Pharmacy (NABP) released a list of the most counterfeited drugs, which included five drugs commonly prescribed for treating cancer or managing side effects of chemotherapy.

- Lupron® (leuprolide)
- Neupogen® (filgrastim)
- Procrit® (epoetin alfa)
- Zofran® (ondansetron)
- Zoladex® (goserelin)

At the same time, NABP also released more stringent licensing standards and other uniform regulations that it wants member boards and the wholesale drug industry to adopt. Both actions coincided with the release of a federal report, which details a plan to crack down on counterfeit drugs.

In addition to new drug-tracking devices, such as a radiofrequency identification tag concealed behind the prescription label, the report calls for tougher criminal penalties for counterfeiters who face up to 10 years in prison for tampering with drug labels and only three years for tampering with the drug itself. The stiffer penalties and new technology are among several anti-counterfeiting measures outlined in a report released by the Food and Drug Administration. The report is available at: *www.fda.gov/oc/initiatives/counterfeit/report02_04.html.*

HHS Issues Final Rule for Bar Codes on Drugs and Blood

On February 25, Health and Human Services (HHS) Secretary Tommy Thompson announced the FDA's final rule requiring bar codes on the labels of most prescription drugs and on certain over-the-counter drugs that are commonly used in hospitals and dispensed pursuant to an order. At a minimum, each bar code for a drug will have to contain the drug's National Drug Code number. This information will be encoded within the bar code on the label of the product. Companies also may include information about lot number and product expiration dates.

HHS said the bar code rule is designed to support and encourage widespread adoption of advanced information systems that, in some hospitals, have reduced medication error rates by as much as 85 percent.

The FDA estimates that the bar code rule, when fully implemented, will help prevent nearly 500,000 adverse events and transfusion errors over 20 years. Furthermore, FDA maintains that the economic benefit of reducing healthcare costs, reducing patient pain and suffering, and reducing lost work time due to adverse events is estimated to be $93 billion over the same period.

The final rule applies to most drug manufacturers, repackers, relabelers, private label distributors, and blood establishments. New medications covered by the rule will have to include bar codes within 60 days of their approval; most previously approved medicines and all blood and blood products will have to comply with the new requirements within two years.

Hospital Radiation Services Take a "Hit" in 2004 under Medicare

by Lynn M. Jones, MHA

Hospital-based radiation departments are experiencing a significant "hit" in Medicare reimbursement in 2004 compared to 2003 as a result of the final outpatient prospective payment rule. Most of the reimbursement reductions are occurring in facilities offering intensity-modulated radiation therapy (IMRT) and high-dose radiation (HDR).

While each hospital is different, our analysis compared two "typical" hospital models and their estimated Medicare revenues in 2002, 2003, and 2004 (see table below). These examples were developed using different workloads and different treatment capabilities. Brachytherapy is not included in this analysis. In our example, Hospital A treated more than 35 patients daily with one linear accelerator and provided no special procedures. Hospital B offered IMRT and HDR and treated more than 65 patients daily with two linear accelerators.

From 2002 to 2003 both hospitals experienced significant improvement in their reimbursement for radiation services. Hospital A (no IMRT and no HDR) saw a 74 percent increase and Hospital B (with IMRT and HDR) had a much smaller increase of 10 percent. However, from 2003 to 2004, both hospitals experienced significant decreases in revenue from radiation services. Hospital A (no IMRT and no HDR) had a decrease of 37 percent, while Hospital B (with IMRT and HDR) saw only a 17 percent decline in revenue from radiation services.

It is not until you compare these reimbursement changes over the full three-year period (2002 to 2004), however, that the full picture is revealed. Such a comparison shows that Hospital A (no IMRT and no HDR) had a 9.8 percent *gain* in revenue from radiation services from 2002 to 2004. On the other hand, Hospital B (with IMRT and HDR) saw an 8.5 percent *loss* in revenue from radiation services in that same time frame. Overall, our analysis shows that Hospital A (no IMRT and no HDR) came out ahead and reveals a gap of approximately 18 percent between Hospital A and Hospital B (with IMRT and HDR) when looking at revenue from radiation services between 2002 and 2004.

This finding is troubling and clearly shows the need for the Centers for Medicare & Medicaid Services (CMS) to review the impact of its 2004 hospital rule changes on radiation services. From a hospital's perspective, the revenue decrease is problematic because hospitals have already invested in newer technologies and treatments requested by physicians and patients. The acquisition of new technology and services have driven hospital costs higher between 2002 and 2004 due to capital costs, increased technical staff time for treatment planning, and higher wages for more skilled staff.

While many in the oncology community are calling for a study on how these rule changes affect hospital operations, maybe we should first consider the fact that Medicare bases its rule changes on data provided by the facilities charging for the services. Hospitals historically have not done a good job of billing for their services. And hospitals billing for new technology *must* use different billing habits if they are to accurately capture revenue for these procedures. Here are a few tips:

- Make sure that radiation services are being accurately billed for every appropriate charge.
- Ensure that HCPCS code 77418 (IMRT Delivery) is billed correctly. In 2004 this code is being reimbursed at $294.11—a 36 percent decrease from the $400 payment rate in 2002 and 2003.
- Make sure that HCPCS code 77301 (IMRT Planning) is billed correctly. Remember that HCPCS codes 77280-77295 (simulations) and 77305-77315 (isodose plans) are *not* separately payable when code 77301 is submitted. In 2004, 77301 is being reimbursed at $850, a $25 reduction from 2003.
- Ensure that HCPCS code 77295 (3-D simulation) and 77336 (weekly physics consult) are billed correctly, when these services are performed.
- Make certain you are billing *separately* for the radiation source used with HDR treatment. In 2003 the cost of the source was bundled in with the procedure cost.

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Comparison of Medicare Reimbursement in 2002–2004

	2002 Revenue	2003 Revenue	2004 Revenue	% Change 2002 to 2003	% Change 2003 to 2004	% Change 2002 to 2004
Hospital A*	$902,500	$1,566,300	$991,300	74%	(37%)	9.8%
Hospital B+	$6,870,800	$7,584,600	$6,287,900	10%	(17%)	(8.5%)

*Hospital A treats more than 35 patients a day with one linear accelerator and no IMRT or HDR.
+Hospital B treats more than 65 patients a day with two linear accelerators and offers IMRT or HDR.