April Reductions to Pass-Through Payments

Until now, the Medicare program has paid for cancer drugs at 95 percent of average wholesale price (AWP). According to the Centers for Medicare and Medicaid Services (CMS), "effective for services on or after April 1, 2002, a uniform reduction of 63.6 percent applies to transitional pass-through payments made under OPPS [the hospital outpatient prospective payment system]." For pass-through drugs, this payment reduction will be implemented differently based on three classes of drugs (sole-source, multi-source, and generic) that are assigned by CMS. The agency has not clearly defined each of these classes, although it has recently advised providers how to calculate payment reductions by item in its latest OPPS update.

In a nutshell, hospitals will be reimbursed 78 percent of AWP for sole-source drugs (and probably for most new drugs), 73 percent of AWP for multi-source drugs, and 62 percent of AWP for generics.

How did CMS come up with these numbers? Read on.

Sole-source drugs are considered to have a base APC rate of 68 percent of AWP, leaving 27 percent of AWP subject to reduction (e.g., 95 percent minus 68 percent equals 27 percent). CMS took the 27 percent and multiplied that by 100 percent minus the uniform reduction—63.6 percent. This results in a 9.8 percent pass-through payment. The next step is to add the 9.8 percent to the 68 percent APC rate, which results in 78 percent of AWP, the amount the hospital will be reimbursed. New drugs are likely to be in this category. ACCC is working to encourage CMS to raise the base rate to protect a larger portion of the payment from the pro rata reduction, but there is no guarantee that this will happen.

Confused? Don't feel bad. The calculation is complex and difficult for everyone to understand.

Multi-source drugs are considered to have a base APC rate of 61 percent of AWP, leaving 34 percent of AWP subject to reduction (e.g., 95 percent minus 61 percent equals 34 percent). CMS took the 34 percent and multiplied that by 100 percent minus the uniform reduction, still 63.6 percent. This results in a 12.4 percent pass-through payment. Take the 12.4 percent and add the 61 percent APC rate, which results in 73 percent of AWP, the new payment.

Moving along to generic drugs. Generics are considered to have a base APC rate of 43 percent of AWP, leaving 52 percent of AWP subject to reduction. Again, CMS took the 52 percent and multiplied that by 100 percent minus 63.6 percent. This results in a 19 percent pass-through payment. Take the 19 percent and add the 43 percent APC rate. The result: 62 percent of AWP is the new payment. This amount will probably cover a hospital's costs, but it is also likely that the 68 percent for sole-source drugs probably will not.

CMS believes that drug administration costs include all infusion center costs and pharmacy costs. Unfortunately, this is often not the case. As CMS decreases payments based on AWP, hospital pharmacy costs will go unreimbursed. These costs are an integral part of cancer care and patient safety. ACCC will urge Congress to require a study of such costs and the need for them to be appropriately reimbursed.

CMS will update drug payments annually on January 1 of every year. That means AWPs of oncology drugs that come into effect April 2002 will stay in effect until January 2003. CMS will use the most recent version of AWP from the *Red Book*. However, the agency will not use monthly updates. Instead, CMS hopes to be able to use the October updates, if these are available. If they are not, CMS will use the July updates. Payment is set to the median price of the generic versions or the lowest of the prices of the brand versions from the *Red Book*.

New C codes covered include those approved for Jan. 1, 2002, and those approved for April 1, 2002. The oncology drug additions include C1066 satumomab pendetide (OncoScint), C9115 zoledronic acid for injection (Zometa), C1774 darbepotein alfa (Aranesp), and C1775 FDG, Fluorodeoxyglucose F18.

Devices have been added to procedure codes, so the pass-through portion will be reduced. However, devices can still be billed with the procedure. Oncology procedures with device additions include infusion codes Q0081, Q0084, and Q0085; radioelement application codes 77761-77778; and brachytherapy codes 77781-77784, and 77799.

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CMS Creates APC Advisory Panel

The Advisory Panel to the Centers for Medicare and Medicaid Services (CMS) held its second meeting in late January 2002 in Baltimore, Md. CMS estab-

…in oncology, the same intervention can take five minutes with one patient and 50 minutes with another.

PHOTOGRAPHS/EYEWIRE

lished the Advisory Panel to counsel the agency on issues related to ambulatory payment classification (APC) groups. The panel announced that it would make recommendations to CMS on appropriate changes to the facility coding of "evaluation and management" (E/M) visits in the outpatient setting.

Today, these codes are a source of much confusion. Their descriptors focus on the time a physician spends with patients and do not indicate whether hospitals should bill for other resources through these codes. In 2001 CMS added to the confusion by asking hospitals to define the codes for themselves and use them so they accurately reflect non-physician hospital resources such as nurse and dietitian time. Compliance and audit concerns have kept many hospitals from pursuing this option. Those hospitals that have set up their descriptors and used the codes have created so much variation among facilities that oversight has become difficult for CMS to manage.

As a result, the APC Advisory Panel is considering major changes to the E/M coding system.

Rather than using existing physician codes and descriptors to bill for the use of other hospital resources such as nurses, dietitians, and social workers, the panel is considering a new set of codes that would allow hospitals to bill for resources according to the time spent by staff and/or the level of intervention performed.

Three options for clinic codes were published on the CMS web site for comment and were discussed at the Baltimore meeting. Reimbursement through the first option would be based on the number of staff interventions performed per patient visit. The time staff members spend with the patient and the number of staff members involved in the visit are not a direct part of the equation. A possible problem with this approach is that, at least in oncology, the same intervention can take five minutes with one patient and 50 minutes with another.

The second option would reimburse the number of minutes staff members spend in direct contact with the patient. The number of interventions and other factors would be addressed only indirectly. One concern about this method is whether the guidelines would create a financial incentive for hospitals to assign tasks to their lowest level staff members, whose modest salaries would increase the hospital's profit margins but whose lack of qualifications could endanger patient care.

The third option bases reimbursement on a "point" system. Points would be assigned according to both the level of complexity of each intervention and the amount of staff time involved. While this option seems complicated, it may be the best approach CMS could take because factors such as diagnosis would be captured, as would the variations of care in different fields of medicine.

There are two additional wrinkles to consider. First, the APC Advisory Panel is debating whether the clinic visit codes should include three or five levels of complexity. There are five levels today, and oncology traditionally uses the more complex and more expensive codes. To collapse five levels into three may well mean the more complicated and costly procedures would receive insufficient reimbursement.

Second, the panel is considering whether to separate the codes for clinic visits from the codes for emergency department (ED) visits. These codes are combined today and present significant problems. The amount of time spent with patients and the type of interventions that are performed are so different in the clinic and the ED that another set of codes is appropriate. The staff members in the ED and the clinic are different, and their concerns about documenting time also differ. Physician codes have proven unworkable for documenting other staff resources, and combining codes for the ED and other departments is just as problematic. ACCC has proposed two sets of codes, each with five levels of care and, at least for the clinic visits, measurements for both time and interventions.

ACCC will continue to monitor the panel's thinking on this matter, and has advised the panel to seek public comment before it makes any final decisions.

Barriers to Rural Cancer Care

While all members of the oncology team face challenges to providing the highest quality of care to patients with cancer, the obstacles for rural providers are often more complicated, according to the President's

Cancer Panel. The panel was established in 1997 by the National Cancer Act and reports on the gaps between research, technology, and the care patients with cancer actually receive.

In 2000 and 2001 the panel held meetings across the country with providers, patients, and advocates to discuss the barriers to quality cancer care in rural America. After hearing the testimony of almost 400 people, the panel released its report in May 2001, which identifies three major factors that impact cancer care in the rural setting: reduced Medicare reimbursement, tougher physician recruitment, and a higher incidence of cancer in the rural population, which tends to be older than the population of urban areas.

Rural cancer providers must address all the barriers to quality care that their urban counterparts face as well as their own unique problems. Together, these problems may be enough to threaten the viability of cancer care in rural areas. The President's Cancer Panel found that, while cancer care costs the same in both rural and urban institutions, Medicare reimbursement levels are significantly lower at rural facilities. Rural costs are as high as urban costs because of the increasing load of paperwork required by the government and insurance companies. What's more, the increasing sophistication of cancer treatment is forcing rural institutions to buy the same expensive equipment that is used in urban cancer centers. Providers are feeling pressure to have the latest technology available so they can

National IRB Starts to Take Burden Off Local Boards

The deaths of patients in clinical trials at Johns Hopkins (in 2001) and the University of Pennsylvania (in 1999) have focused the nation's attention on the Institutional Review Boards (IRBs) that were supposed to be ensuring patient safety in clinical trials at both facilities, and on IRBs in general.

Obviously something went wrong in either the review or the oversight process that allowed these deaths to take place. The question is whether the problems were unique to the two institutions involved or represent a national trend that could endanger research patients in studies anywhere in the country.

Oncology Issues contacted several researchers, all of whom gave us the same answer. The problem—paperwork overload from big national studies keeping local IRBs from policing trials that originate at their own institutions—exists everywhere and threatens all research participants. The National Cancer Institute (NCI) agrees with this point of view and has started work on a national IRB that could remedy the situation.

Institutions doing research are usually affiliated with a number of the large, national trial groups (SWOG, RTOG, ECOG, NSABP, GOG, etc.). These national trials have a variety of sponsors, both academic and corporate, and are set up with data monitoring committees composed of qualified individuals not affiliated with the study. The committees independently review study data and make safety decisions for the study as a whole, following the rules of the NCI's Office of Human Research Protection (OHRP) and the standards of the Food and Drug Administration (FDA) on human research. In fact, safety precautions are built into these large studies. High toxicity levels generate automatic stop orders, and other checks and balances are put in place before the most rudimentary Phase I activity takes place.

While smaller institutions may host these trials as their only research offerings and are, in a sense, protected by the safety efforts of the sponsors, larger teaching hospitals and multi-center groups do original research studies that their on-site, local IRBs are responsible for monitoring. This is where the problem lies. Both the nationally reported deaths occurred in original research studies done at teaching hospitals.

"There's an exhaustive amount of paperwork connected with national studies," Douglas Bailey, Pharm.D., and chair of the IRB for Covenant Health Systems in Knoxville, Tenn., told *Oncology Issues*.

Carl G. Kardinal, M.D., principal investigator of the Ochsner Clinic CCOP and chair of the IRB at the Ochsner Clinic Foundation in New Orleans, La., said that the cancer research program at Ochsner receives more than 100 notices about adverse events in national studies from the FDA every month, and the institution as a whole receives 300 to 500, including reports on related research being done all around the world. Each of these reports has to be reviewed by Ochsner's IRB to determine, among other things, whether the data change the study's risk/benefit ratio, whether the protocol itself needs to be modified, or whether the investigators need to change the consent form and get reconsent from already participating patients. The vast majority of these reports have nothing to do with the research being done at Ochsner, but must be reviewed and signed off on anyway.

John Feldmann, M.D., medical director of cancer services at the Mobile Infirmary Medical Center and senior oncologist at Gulf Coast Oncology, said the information packet for each monthly IRB meeting at the Mobile Infirmary is around 12 inches thick.

"In the course of the study of any investigational drug, the researchers are required to report any adverse reactions that take place," Feldmann told *Oncology Issues*. "This should not be a problem if investigators would use some judgment in their reporting, but they often don't. They report every bad thing that happens to the patients, even if the problem is clearly related to the nat-

offer patients the best hope of surviving their disease. The lower reimbursement levels for rural settings can make the situation untenable.

Rural facilities face the additional challenge of trying to recruit physicians, nurses, and other support staff from smaller local populations. Retaining staff is also more difficult because rural salaries are not competitive with the salaries available at urban institutions. Looking outside a rural community for staff is costly. Even without the salary discrepancies, keeping nonlocal staff members on board is difficult if they are not used to rural life.

The Panel found that these problems were compounded by the fact that 20 percent of the population that lives in rural communities is over age 60 and has a higher incidence of chronic illnesses and a shorter life span compared to their more urban counterparts. The end result is that rural cancer care facilities are facing an increasingly older and less healthy population, and lack the financial and staffing resources necessary to care for that population.

ACCC recognizes the importance of patient access to high-quality local cancer treatment. Forcing rural patients and their families to drive long distances or incur the costs of an out-of-town stay to receive treatment can be an overwhelming stress and negatively affect their quality of life. ACCC will continue to work with Congress and CMS to protect funding for rural cancer centers and will support legislation to assist rural institutions in their recruitment efforts. Rural cancer centers are important to the communities and the patients they serve, and it is vital that they remain viable.

ural history of the disease and not to the drug under study. Local IRBs must evaluate this huge volume of paperwork to see if any of it is really important to the drugs being investigated at their institutions." Feldmann said the reports are also reviewed by the company that makes the drug.

Monica Thompson, program manager for clinical trial protocol services at the University of New Mexico Cancer Treatment Center in Albuquerque, seconded Feldmann's appraisal. "I've seen oncology patients be reported as adverse events when they got into car wrecks," said Thompson. "I was discussing this phenomenon with a colleague who said, 'How do you know the drug didn't cause the patient to get high and crash her car if it's the first time we are using the drug? It could have caused a brain swelling that interfered with her driving.' If she was driving, he's right; but if she wasn't driving, it's useless information."

Kardinal, Feldmann, Thompson, and Bailey all agreed that local IRBs cannot possibly review all the national and international material on large trials that is presented to them, and in the process of trying they end up not having time to monitor the clinical trials going on in-house.

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All four also thought that a national IRB should be set up to review the large group studies and send material to local IRBs only on the trials in which they participate. Without the deluge of irrelevant forms, local boards could adequately oversee the research at their own institutions, checking for design flaws in original study plans and monitoring results as the studies progress.

The NCI agrees. Since Jan. 1, 2001, a pilot national IRB (the Central Institutional Review Board [CIRB] Initiative) has been reviewing protocols. According to Jacquelyn Goldberg, the CIRB administrator, the board meets once a month at the Bethesda, Md., campus of the NCI. Its experts meet the standards set up by the OHRP and fly in from around the country to participate. The new entity currently only reviews cooperative group, Phase III, adult studies.

After the group approves a proposed study, it writes up a record of its deliberations and sends it to the IRBs of the 21 local institutions participating in the pilot project. The local groups determine whether their facility should take part in the trial, and if they decide to go ahead the CIRB becomes their IRB of record and takes care of all adverse event reports and other normal IRB functions.

According to Goldberg, this model is based on the research situation in 1974, when OHRP's regulations were first formulated. Research was more decentralized then, and there was a big emphasis on "local context" and the knowledge local practitioners had of their individual patient populations. The structure of the pilot IRB reflects this concern for local input.

Goldberg told *Oncology Issues* that the NCI hopes to expand the number of local institutions participating in the CIRB Initiative to 100. Until more data are accumulated, the CIRB will remain a pilot project, although its founders hope to make it a full-fledged reviewing body in the future.

For more information on the CIRB Initiative, visit the CIRB web site at *www.ncicirb.org.*

IMRT Update

by Carl R. Bogardus, Jr., M.D.

Two new codes for IMRT (intensity modulated radiation therapy) became effective Jan. 1, 2002. They are 77418 for IMRT Delivery Per Session and 77301 for IMRT Treatment Planning Per Course. The radiation oncologist can continue to bill code 77427, which is the professional component of treatment management for IMRT on a weekly basis.

As noted in the *Federal Register*, the Centers for Medicare and Medicaid Services (CMS) lists the following codes for payment of IMRT planning: 77280, 77285, 77290, 77295, 77300, 77305, 77310, 77315, 77321, 77336, and 77370.

IMRT has been developed to deliver a more precise radiation dose to the tumor while sparing the surrounding normal tissues. Intensity modulated radiation beams are painted across the tumor volume and driven by computer-based optimization planning and delivery techniques. The computer-based optimization process is referred to as inverse planning. Forward planning is the original technique of radiation oncology planning. The use of inverse planning changes the process in which the desired dose to the tumor and the maximum permissible dose to the protected volumes are both specified. The planning computer is then allowed to develop the appropriate plan to achieve these end results, which often include a very complex set of beams with extremely complex blocking.

ACR Policy

The American College of Radiology (ACR) has completed its model policy for IMRT, which includes a number of specific limitations. First, the delivery of IMRT requires the use of a multi-leaf collimator (MLC) with leaves that project to a nominal 1 cm or less at the treatment unit isocenter. Second, MLC may be operated either in the continuous (dynamic) mode or the segmented (step) mode. In the step mode at least five discrete steps are required. Third, compensator-based systems are excluded from the IMRT rules and may not be considered IMRT treatment delivery. Finally, IMRT delivery imposes stringent requirements for patient position and organ motion.

Under ACR model policy, at least one of the following conditions must be met for IMRT to be considered an appropriate therapy. First, dose-limiting structures outside of the primary tumor volume are so close that they require IMRT to assure safety and morbidity reduction. Second, an immediately adjacent volume has been previously irradiated and abutting portals must be established with high precision. Third, the gross tumor volume margins are concave or convex and in close proximity to critical structures. Fourth, only IMRT techniques will decrease the probability of grade II or grade III radiation toxicity compared to conventional treatment.

Under ACR model policy, local Medicare carriers will control billing for the IMRT process by using appropriate regulations established by the local Medicare review policies (LMRP) validated through the Carrier Advisory Committee (CAC). The carriers are not required to submit the codes through the CAC. Individual radiation oncology practices should immediately contact their CAC if they find that the regulations are not as described by the ACR. It will be extremely important for radiation oncologists to adhere to the guidelines related to the support of medical necessity for the use of IMRT.

IMRT is indicated for more than 150 sites under ACR's IMRT model policy. Codes that are not covered in this model policy will require review of the claims by the Medicare carrier on a case-by-case basis to determine coverage.

Considerable documentation is required in the medical record to support the use of IMRT, including, of course, medical necessity. The physician's prescription must define the goals and requirements of the treatment plan, including specific dose constraints for target and critical structures. In addition, a written statement by the physician must document the special need for the use of IMRT rather than the use of conventional three-dimensional planning and delivery. Other required documentation includes a physician-signed IMRT inverse plan that meets the prescribed dose constraints, the use of dynamic MLC or step MLC with a minimum of five steps; detailed documentation of target verification, documentation of immobilization and patient positioning, dose verification with a secondary means of verification, documentation of fluence distribution recomputed in a phantom, and documentation to account for structure motion limitation.

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