Working to Ensure Adequate Reimbursement

ACCC has been working with both the Centers for Medicare and Medicaid Services (CMS) and Congress to help assure that the 2003 ambulatory payment classification (APC) rates for drugs and biologicals clearly recognize and reimburse for cancer care costs. This effort is particularly important because starting January 2003 the majority of drugs and biologicals currently in the pass-through system will become ineligible for further pass-through payments.

ACCC's early efforts are the result of concerns that the agency's data for setting 2003 rates is poor. ACCC has asked the agency to share the 2001 hospital data with providers as soon as possible, so ACCC can begin to 1) identify where the data are lacking, 2) find ways to supplement the data, and 3) suggest a methodology for analyzing the data that will compensate for its shortcomings.

ACCC has also been working to educate CMS on the flaws in its external study conducted two years ago by Kathpal Technologies, which concluded that single-source drugs cost no more than 68 percent of average wholesale price (AWP). ACCC believes the study surveyed too few hospitals on too few drugs, and has asked CMS for more information on whether the hospitals were located in rural or urban settings, or if they were teaching hospitals, to better gauge if they were representative of the nation's hospitals. Furthermore, the study did not include many *new* drugs.

ACCC has drafted a legislative proposal for consideration by congressional committees with jurisdiction over the Medicare program that would:

1 *Maintain separate APCs for drugs and biologicals.* Given the significant clinical and financial differences among pass-through drugs, ACCC believes that any attempt to bundle cancer drugs and biologicals into APCs would diminish the ability of hospital outpatient departments to provide these therapies to their patients. Past efforts to bundle cancer costs failed to fully capture the individualized nature of drug treatment regimens or the significant variations in the type, amount, and cost of drugs required by individual cancer patients.

PHOTOGRAPH BY C. LEE/PICTURE QUEST

2 Apply a "reasonableness test." If, after applying its data and methodology to set 2003 APC rates, CMS finds the rates are significantly below payment rates at the start of 2002, ACCC's proposal for legislation would require the new rates to be increased until they are no lower than 95 percent of January 2002 rates. CMS' inadequate and incomplete data cannot justify any more drastic payment cuts. In addition, ACCC believes that any major changes in payment levels will likely disrupt patient access and should be considered carefully.

3 *Call for a pharmacy service cost study.* CMS continues to argue that pharmacy service costs incurred by a hospital to ensure safe and effective delivery of cancer care are currently reimbursed as a part of a chemotherapy administration payment. Such services include the storage and spillage of drugs, compliance with safety protocols and regulations, and establishing dosage regimens that avoid drug interactions and contraindications. Hospitals that ACCC has talked with suggest otherwise. ACCC's proposal for legislation calls for a study of these costs to quantify how extensive they are and how they are reimbursed.

4 *Protect future pass-through payments.* This legislative proposal would prohibit draconian pro-rata reductions to pass-through payments, such as the 63.6 percent cut implemented April 1, 2002. ACCC and other oncology organizations believe that such drastic cuts make it difficult for hospitals to meet their costs and keep their cancer service line viable. CMS would be prohibited from instituting pro-rata reductions greater than 20 percent, even when the 2.5 percent spending cap is breached. When reductions are as significant as those implemented in 2002, they undermine the very intent of the pass-through system—to protect patient access to cancer therapies and new technologies in hospital outpatient departments.

—by Saira Sultan, J.D.

Throwing Out AWP

Discussions about replacing AWP methodology in the office-based setting with a payment system that more accurately reflects the cost of acquiring drugs continues on Capitol Hill. Three committees—two in the House and one in the Senate—have jurisdiction over this sensitive issue. Unlike last year, when only the House Energy and Commerce Committee went as far as drafting a proposal, this year all three committees are working on the issue.

Prompting all this activity, in part, is CMS Administrator Thomas Scully's statement that if Congress fails to act this year, he will reform AWP administratively next year. If he does this, Scully would take away Congress' ability to spend the savings from AWP reform on other legislative priorities. Unfortunately, the three committees are a long way from agreeing on what that reform should look like—fueling speculation as to whether Congress will be able to take action before adjourning for the year.

The politically powerful House Ways and Means Committee has released a draft of a competitive bidding model to replace the controversial AWP. Under this proposal, pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) would submit blind bids to CMS for all Part B drugs at certain prices and dosages. These bids would include information on the bidder's ability to deliver the drugs in a timely manner and other "quality" factors. CMS would review the pricing and dosage data in the bids and set some type of weighted average price. Still under consideration at press time are such details as methodology for setting the price, adding a dispensing fee, and whether GPOs with outlier bids would be barred from the program for a year. The elimination process would be intended to encourage bidders to submit the lowest possible prices to CMS to ensure that the program will no longer be paying inflated drug prices.

CMS would be given broad discretion to evaluate the other "quality" factors in the remaining bids. A set of Part B dealers would be selected from these bids that would then be able to sell drugs to physicians participating in the Medicare program.

Still under debate is whether physicians would negotiate directly with GPOs or whether the GPOs would be required to sell drugs at the prices submitted to CMS. Theoretically, physicians and GPOs would pressure pharmaceutical companies to lower their prices, ensuring that Medicare would not be paying inflated prices for drugs.

Presumably, CMS would create a system by which bidders would have to sell to any and all participating physicians. While mid-year bids would be accepted for new drugs

Good-bye to Local Medical Review?

The General Accounting Office (GAO) is in the process of interviewing Medicare carriers to determine whether the local medical review policies (LMRPs) currently used by individual carriers should continue. Carrier decisions affect newly introduced medical items, services, and drugs.

The GAO has been instructed by the Medicare Payment Advisory Commission (MedPAC) to visit small, intermediate, and large carriers in a variety of states to evaluate the situation and determine whether there are "conflicting" carrier or intermediary policies. MedPAC has proposed eliminating local medical carrier reviews and instituting one national carrier decision. Certainly, there would be less conflict between the states and carriers if a national carrier decision were instituted, but local carriers have unique knowledge of the people they serve, their local situation, and local provider practice patterns that are important to medical decision-making. Resolution of this issue will have to wait until the GAO has finished its carrier visits and had time to review the information gathered.

ILLUSTRATION/EYEWIRE

coming to market, the annual bidding system would not account for mid-year price changes on existing drugs. CMS would also be required to ensure that every Part B drug has at least one bid.

This proposal raises several questions:

- What if participating dealers sell to rural providers at very high prices?
- What if several practices band together to obtain lower prices and rural providers are left behind?
- Will rural providers be forced to accept smaller margins? If so, is that contrary to Medicare policy to bring access to rural areas?
- What will practices do when a new drug comes to market but the mid-year bidding process has not yet set a Medicare reimbursement rate?
- How does this proposal account for single-source drugs whose manufacturers are not willing to negotiate?
- How does this proposal expect physicians to absorb the cost for mid-year price changes?

CMS Offers Guidance on Self-Injectable Drug Coverage

On May 15 CMS issued a program memorandum to Medicare contractors to determine whether an injectable drug is covered by Medicare. The guidance states that drugs that are administered more than 50 percent of the time by beneficiaries will be excluded from Medicare coverage. Carriers (private insurance companies that process and pay claims) must use the new guidance to make coverage decisions about individual drugs. The memorandum will go into effect August 1. ACCC and others in the cancer community are considering asking CMS for a withdrawal and/or clarification of this memorandum.

Of course, the primary concern remains—offsetting the practice expense side of the equation.

AWP reform is politically tied to several highly contentious issues, including the prescription drug benefit, the budget deficit, and election year politics. The House Energy and Commerce Committee continues to support its average sales price (ASP) model, while the House Ways and Means Committee believes that a competitive bidding model is more appropriate. There are early indications that the two committees may be willing to work out a compromise. The Senate Finance Committee has not yet drafted anything, but is more interested in the ASP proposal. With mounting pressure on Congress to pass some type of drug benefit this year plus deficit budget politics, there is a great deal of interest in finding cost-saving proposals like these that could be used, in part, to fund a drug benefit.

ACCC will continue to ensure that the cancer community has input into the development of this proposal, as well as any other proposed AWP reform models.

Higher Than Expected FY 2003 Medicare Inpatient Rates

Hospitals serving Medicare patients would receive a 2.75 percent increase in payment rates for FY 2003 inpatient services under a rule that CMS proposed May 8 and that appeared in the May 9 *Federal Register*. The boost would be 0.5 percent higher than the rate hospitals had expected to receive starting October 1.

The updated rate, which CMS bases on a FY 2003 market basket update of 3.3 percent minus the standard 0.55 percent, indicates that the agency expects the costs of goods and services for acute-care hospitals to be higher than it originally assumed for the next fiscal year. (Many hospitals have already formulated their budgets based on the lower estimate.)

"The update should be a pleasant surprise for hospitals," said CMS Administrator Tom Scully in an agency release.

Since the increase will not be distributed equally among services, it is not certain how this will affect cancer programs. In November 2002, CMS will publish 2003 relative weights, using 2001 data.

CMS also announced that hospital costs in FY 2002 have been lower than expected, meaning hospitals received a Medicare inpatient rate increase that was relatively higher than expected. The government estimates that the current market basket level for 2002 is 2.8 percent, which is just 0.05 percent above the payment rate update the hospitals received for the year.

CMS will issue a final regulation later in 2002 after the comment period is completed.

Physician Payment Updates

On March 21, 2002, the chair of the Ways and Means Committee, Bill Thomas (R-Calif.), and the chair of the Health Subcommittee, Nancy Johnson (R-Conn.), sent a letter to CMS Administrator Thomas Scully about physician payment updates. Currently, physician payments are calculated using the sustainable growth rate (SGR) system, which resulted in the 5.4 percent decrease in this year's physician payments. The Office of the Actuary (OACT) and the Congressional Budget Office (CBO) predict that these decreases will continue through 2005, resulting in a 2005 physician conversion factor that will be less than the conversion factor used in 1993.

The lawmakers told CMS that they believe these decreases are the result of several flawed assumptions and errors in the SGR system and ought to be rectified administratively by CMS. They point out that, while there is strong support in Congress

PHOTOGRAPH/EYEWIRE

Oral Anti-Cancer Therapies

The Access to Cancer Therapies Act of 2001, sponsored in the Senate by Sen. Olympia Snowe (R-Maine) and in the House by Rep. Deborah Pryce (R-Ohio), has broad bipartisan support, and its chances of being sent to the President's desk seem to be improving. The Senate version now has 47 co-sponsors and the House bill has almost 300. ACCC has long supported this legislation and has worked with the cancer community towards its passage. At its annual meeting, ACCC members went to Congress to advocate on behalf of this legislation.

Today, Medicare covers cancer drugs provided in the physician's office or hospital outpatient department as long as they are given "incident to" a physician's service and have an injectable equivalent. This legislation would broaden Medicare's coverage to include all oral anti-cancer therapies, not just those with an injectable equivalent, allowing Medicare to keep pace with technological advances in cancer care.

The upcoming November elections have put some pressure on Congress to take home a prescription drug benefit. However, large differences between Democrats and Republicans on how to structure and pay for the more comprehensive benefit seem an insurmountable barrier to passage. Along with the looming budget deficit and the surrounding politics, only a smaller benefit seems workable this year. The Snowe-Pryce legislation may just fit the bill, allowing members of Congress to show their concern for rising prescription drug costs and seniors' ability to pay for much-needed drugs. This legislation also signals support for the cancer community and does so without breaking the bank or embroiling members in a partisan battle.

ACCC will continue to work towards passage of the Snowe-Pryce legislation so that Medicare better reflects changes in technology that influence patient access to new treatments. To learn more about this, visit ACCC's public policy web site at *www.accc-cancer.org/publicpolicy.*

for enacting legislation to neutralize the reimbursement cuts, the price for these fixes is extremely high due to the flaws in the SGR that project further cuts in upcoming years.

The following is a list of factors that Representatives Thomas and Johnson believe resulted in flawed and inaccurate updates to the physician conversion factor:

1 One of the factors used in the calculation of the SGR is the Medicare Economic Index (MEI). The MEI represents changes in productivity, but only takes labor productivity into account and omits non-labor factors such as equipment, medical materials, and supplies. The lawmakers support MedPAC's recommendation that CMS undertake a multi-factor productivity study to determine the effect labor and non-labor factors have on productivity.

2 One of the underlying assumptions in the SGR system is that physicians increase their patient volume to offset decreases in the conversion factor. However, CMS believes that physicians only increase their volume to offset about 30 percent of any rate decrease. This assumption means that, in order to meet total expenditures under the system, much larger reductions in rates are needed. Furthermore, CMS assumes that this 30 percent increase in volume offset can continue year after year. The 30 percent assumption is based on data from 1994–1996, prior to the implementation of the SGR system. CMS has failed to analyze recent data under the current system to justify this assumption.

3 The lawmakers argue that inherent in the 30 percent offset theory is the idea that physicians have a target income. Under the assumption that decreases in reimbursement result in changes in productivity, then one must take into account other factors that impact income. Specifically, lawmakers cite changes in the marginal tax rate. They maintain that such changes, under CMS logic, should result in a decrease in a physician's volume of services and should be factored into the SGR.

4 According to the OACT, professional liability insurance cost has a weight of 3.2 percent in the total MEI. However, CMS estimates that this insurance cost increased by 7.3 percent in 2001, and will increase by 4.0 percent in 2002 and 4.6 percent in 2003. Due to CMS' underestimating the cost of insurance premiums, as well as future increases in the conversion factor, the lawmakers request that CMS re-examine their assumptions about the costs of malpractice insurance and its impact on the total SGR system.

5 While CMS takes into account additions to Medicare coverage, it is only for additional coverage that is the result of statutory changes. Administrative changes to national coverage, like positron emission tomography (PET), are not taken into consideration. This means that the SGR underestimates the actual cost increases in any given year.

6 CMS inaccurately estimated the GDP growth and fee-for-service (FFS) enrollment for 1998 and 1999. Since the SGR is cumulative, these corrections would result in an increase in the physician update. The lawmakers point out that the Balanced Budget Refinement Act of 1999 (BBRA) gave CMS the authority to administratively correct data in the SGR system. The AMA estimates that these data errors have artificially lowered Medicare funding for physician services by $20 billion.

Thomas and Johnson have requested that CMS re-evaluate these problems and administratively fix the flaws and errors in the SGR system. Rep. Johnson recently introduced H.R. 3882, the Preserving Patient Access to Physicians Act of 2002, to address many of these concerns.

The Effect of Medicare's Transitional Pass-Through Payments on Oncology Services

by Mary Lou Bowers, M.B.A., Dorothy Knight, M.P.M., and Linda B. Gledhill, M.H.A.

Prior to April 1, 2002, the Medicare program paid for cancer drugs at 95 percent of average wholesale price (AWP). Effective April 1, 2002, the Centers for Medicare and Medicaid Services (CMS) applied a uniform reduction of 63.6 percent to transitional pass-through payments for drugs and biologicals under the hospital outpatient prospective payment system (OPPS).

Effective April 1, 2002, hospital outpatient departments will be reimbursed for pass-through drugs at 78 percent of AWP for sole-source drugs, 73 percent for multi-source drugs, and 62 percent for generic drugs. Devices have been added to procedure codes, so the pass-through portion will be reduced. However, devices can still be billed with the procedure.

Calculating Your Medicare Payment

According to CMS, the 63.6 percent reduction is based in part on the agency's analysis of the acquisition costs of certain drugs. Medicare stated that pass-through funds pay for 25 percent of all devices, 27 percent of all sole-source drugs, 34 percent of all multi-source drugs, and 53 percent of all generic drugs.

Here's how to calculate the impact of these payment reductions for each of the drugs and devices your cancer program uses.

For devices

Step 1 Multiply your charge for each procedure times your department(s)' cost-to-charge ratio (i.e., $100 for procedure x .50 the cost-to-charge ratio = $50).

Step 2 Multiply that amount by 25 percent (i.e., $50 x .25 = $12.50).

Step 3 Multiply that amount by 36.4 percent (i.e., $12.50 x .364 = $4.55). This dollar amount is your expected Medicare payment.

Remember that Medicare stated that 75 percent of the device payment has been bundled into the procedure payment.

For drugs

According to Medicare's March 28, 2002, Program Memorandum Transmittal (A-02-026), the formula for transitional pass-through drugs is as follows. This example is for the sole-source drug trastuzumab (Herceptin®), 10 mg.

Step 1 Multiply the patient's co-pay (listed in the OPPS Addendum B) by 5 to get the amount of the non-pass-through portion (i.e., $7.56 copay x 5 = $37.80, non-pass-through portion).

Step 2 Subtract the non-pass-through amount from the total Medicare payment amount. The remaining amount is the pass-through portion subject to reduction (i.e., $52.83, APC payment rate, minus $37.80 = $15.03, the pass-through portion).

Step 3 Multiply the pass-through portion by 36.4 percent for the adjusted pass-through payment (i.e., $15.03 x .364 = $5.47, the adjusted pass-through portion).

Step 4 Add the adjusted pass-through payment to the non-pass-through payment (Step 1) for the total payment to the provider (i.e., add $5.47 to $37.80 = $43.27, total payment to the provider).

Step 5 Subtract the patient's original co-payment amount from the total payment to the provider (Step 4) for the Medicare payment amount (i.e., $43.27 minus $7.56 co-pay = $35.71, total Medicare payment amount).

If you want to know which classification a particular drug belongs to (sole source, multi-source, or generic), you can divide the total adjusted payment to the provider by the AWP for the drug as published in the July 2001 *Red Book*. If the percentage is 78 percent, the drug is considered sole source, 73 percent multi-source, and 62 percent generic.

What this means to the cancer center bottom line depends on how well you manage your charge process. APC payments will be changed by CMS, if outpatient cancer centers record and supply good data to CMS about charges and costs to provide the services.

In addition, Medicare has clearly stated that pharmacy costs, other than billable drug costs, are reimbursed through drug administration payments. Most hospital outpatient cancer programs do not include pharmacy service costs or pharmacy revenue in their budget. This means current drug administration charges do not include any pharmacy costs. Also, radiation oncology charges need to cover all device costs.

On Jan. 1, 2003, the majority of drugs currently on the pass-through will no longer be eligible for a pass-through payment and instead will receive only an ambulatory payment classification (APC) payment. In 2003, it is possible that all device costs will be bundled into the procedure.

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