HIGHLIGHTS of the

Final Hospital OPPS Rule for 2003

by Mary Lou Bowers, M.B.A.

The final hospital outpatient prospective payment system (OPPS) rule was released by the Centers for Medicare and Medicaid Services (CMS) on Oct. 31, 2002. This rule announces final payment rates for hospital outpatient services beginning Jan. 1, 2003.

Unquestionably, the biggest change in the OPPS for 2003 is the termination of pass-through payments for most drugs and devices. The law requires that 1) pass-through payments be made for not less than two nor more than three years and 2) at the conclusion of this period that payment for drugs and devices be incorporated into the basic ambulatory payment classification (APC) system. Most current pass-through items have been paid based on this status since the inception of the OPPS on Aug. 1, 2000, and their eligibility will end effective Jan. 1, 2003.

For drugs, the final regulation affirms the policy stated in the proposed rule: to package (or bundle) drugs with a median cost per dose of less than $150. Beginning Jan. 1, 2003, these drugs will no longer be paid separately in their own APC, and their cost will be included in the cost of the associated procedure (e.g., chemo by infusion).

The American Hospital Association supports this provision to bundle drugs, while the Association of Community Cancer Centers does not. Given the significant clinical and financial differences among pass-through drugs, ACCC believes that any attempt to package or 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 drugs failed to fully capture the individualized nature of drug treatment regimens or the significant variations in the type, amount, and cost of the drugs required by individual cancer patients.

In the final rule, CMS reiterates its intent to review the impact of the packaging (bundling) policy. Unless there is evidence that packaging interferes with beneficiary access to needed drug treatments in the hospital outpatient department, greater packaging is likely.

In 2002, more than 358 drugs, biologics, and radiopharmaceuticals were paid separately, either as a pass-through drug or a separate drug APC. In 2003:

- 161 drugs will be assigned to an APC that is specific to the drug and continue to receive a separate payment, generally at much lower payment rates. Ninety percent of these drugs will have lower reimbursement amounts in 2003, and the combined reduction will come to around $293 million. CMS attempted to reduce the impact of these reductions with a so-called "dampening policy" (more detail below), but was not particularly effective. Without the dampening policy, the reduction would have been $310 million.
- 13 drugs will continue to be paid as pass-through drugs at 95 percent of AWP. (These drugs have not been on the market for two years or more.)
- 165 drugs will be bundled into the APC payments for their associated administration procedures and no separate payment will be made for them. At stake is about $270 million that these 165 drugs were given in separate payments in 2001. These funds are not recovered in the administration payments, although CMS states that if hospitals charge appropriately they will recover their costs (see Table 1).

Although the final rule bundled more than $270 million in drug payments into their associated procedures, the payment rates for five of the six most commonly used administration procedures decreased, as shown in Table 1. Thus, Medicare reimbursement to the hospital will be less in 2003 than it was in 2002, *and* there will be no separate payment for those 165 drugs.

CMS based the lower payment rates in the 2003 rule

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on three principles. First, CMS *only* intends the APC payment to cover a product's acquisition cost because the agency believes that pharmacy costs are paid for elsewhere, namely in the administration payment of the drug. Second, CMS has stated that OPPS payment rates are *only* intended to compensate for approximately 82 percent of the actual cost to hospitals. Third, because hospitals do not report their drug acquisition costs to CMS, the agency uses hospitals' charges to calculate the estimated costs of drugs. Using this technique, CMS often sets payment rates that are *less* than the actual acquisition costs.

In the final rule, CMS announced a new "dampening" policy instituted to lessen the impact of the reductions. The policy is based on a loss threshold of 15 percent for the 2003 rate compared to the 2002 rate. Reductions greater than 15 percent are limited to 15 percent plus half of the additional reduction amount over 15 percent. However, as seen in Table 1, the reductions in drug payment rates for 2003 are substantial even after application of the dampening policy.

The lack of payment increases in drug delivery procedures is a direct result of hospitals charging inappropriately. CMS altered its bundling requirements, moving pharmacy preparation and overhead out of the drug payment and into the procedure payment for which the drug is given. In cancer care those procedures are the infusion administration codes.

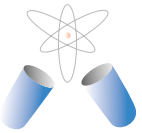
In summary, the final rule shows little improvement over the substantial reductions announced in the proposed rule.

CONTINUING PASS-THROUGH PAYMENTS AND OTHER CHANGES

Pass-through payments will continue for drugs and devices that first became eligible for such a payment after Jan. 1, 2001. The final rule identifies 17 drugs and seven device categories that will receive pass-through payments in 2003, including Zometa®, Faslodex®, and Neulasta.™ Other new items will be added to the list throughout 2003. At this time, CMS estimates that there will be no pro rata reduction in 2003.

The final regulation includes several other changes important for payments made under the outpatient system for drugs. These include:

Zevalin: No Longer a "Drug"



CMS has concluded that Zevalin™ is neither a drug nor a biological. The final rule states: "… [Zevalin] consists of a radioactive isotope that is delivered to its target tissue by a monoclonal antibody. Because of the specific requirements associated with delivery of radioactive isotope therapy, any product containing a therapeutic radioisotope," will be included in a section of the statute used for X-ray, diagnostic lab test, radium, etc.

Because of this decision, Zevalin is no longer eligible for pass-through payments. However, payment will still be made under two new technology APCs. For Y-90 Zevalin, APC 725 will reimburse $20,000; for IN-111 Zevalin, APC 718 will reimburse $2,750.

There are two significant implications of the CMS decision to pay for this product as a new technology APC rather than as a pass-through drug or biological. First, payments will not count against the limited pass-through pool; in the proposed rule, CMS had projected that this product would have very substantial expenditures. Second, making payment in a new technology APC gives CMS discretion in setting the payment rate.

- *Methodology*: CMS acknowledged that there may be problems with the cost-to-charge ratio methodology used to determine costs from billed charges, especially for high-cost items. The agency said that "this issue merits further study, and we expect to address it further in the future."

- *C Codes*: CMS acknowledged the concern about delays between FDA approval of a new drug and the assignment of a Medicare code for payment purposes. The final rule stated: "We are conscious of the need to streamline this process and we will continue to seek ways to do so."

- *Outliers:* About $375 million is available for outlier

Table 1. Reductions in Drug Payment Rates for 2003 After Application of the Dampening Policy

APC	Description	2002 Base APC Payment	Final 2003 Base APC Payment	Final 2003 vs. Final 2002	2003 Final vs. 2002 % Difference
0116	Chemotherapy by a method other than infusion	$46.32	$40.43	-$5.89	-13%
0117	Chemotherapy by infusion	$205.14	$187.98	-$17.16	-8%
0118	Chemotherapy by both infusion and other technique	$214.81	$286.02	$71.21	33%
0120	Infusion therapy other than chemotherapy	$157.80	$113.70	-$44.10	-28%
0353	Level I injections	$20.87	$20.72	-$0.15	-1%
0359	Level II injections	$91.63	$59.12	-$32.51	-35%

Source: Centers for Medicare and Medicaid Services

HOPPS and "Functional Equivalence"

by David K. King, M.D., F.A.C.P.

On Nov. 1, 2002, the Centers for Medicare and Medicaid Services (CMS) published its final hospital outpatient prospective payment system rule for calendar year 2003. In addition to making dramatic reductions in payment rates for most cancer drugs and biologicals, the rule implemented a deeply troubling new "functionally equivalent" standard that will substantially affect Medicare beneficiaries' access to new technologies. This new policy violates the plain language of the Social Security Act (SSA) and was implemented without any notice and opportunity for public comment.

The Association of Community Cancer Centers (ACCC) is deeply troubled that the adoption of a "functionally equivalent" standard will deny Medicare beneficiaries access to new, innovative therapies. Paying for a new drug at the same rate as an old drug, even when the acquisition cost for the new drug is higher, will reduce providers' flexibility in providing the most clinically appropriate treatment for a particular patient. Moreover, without the promise of adequate payment rates, innovation will be discouraged. Manufacturers simply will not devote precious resources toward improving current therapies or in developing new therapies that could be seen as "functionally equivalent" to another product.

Not only is CMS' "functionally equivalent" standard contrary to the plain language of the statute, but it also was implemented without any mention whatsoever in the proposed rule. Clearly, had CMS provided notice in the proposed rule regarding the potential implementation of this policy, ACCC would have vigorously voiced the opposition of its members, citing concerns about the plausibility of the agency making such determinations and the potentially adverse impact on innovation and improved patient care. ACCC believes that CMS should not implement such a significant policy without using the appropriate notice and comment process.

The new policy is particularly troubling in cancer care, where treatment regimens are complex and where one drug that is only modestly beneficial for one patient may be significantly beneficial for another. This is precisely why Congress created the transitional pass-through system for new drugs, requiring CMS to collect data on new therapies for a few years before establishing prospective payment rates for them. ACCC firmly believes that physicians are the only ones who should determine that one drug is an appropriate substitute for another drug, and this decision should be made only on an individual patient basis.

PROCRIT AND ARANESP

In the final rule, CMS determined that Aranesp™ is "functionally equivalent" to Procrit™ and thus is no longer eligible for transitional pass-through payments. Currently, the language of the SSA grants new drugs and biologicals, such as Aranesp, transitional pass-through status for two to three years, during which time they are to be reimbursed at 95 percent of their average wholesale price (AWP). Payment reductions may occur but only on an across-the-board, pro-rata basis in the event that CMS projects that the statutory cap would be exceeded. The statute does not authorize the agency to eliminate an individual drug's transitional pass-through status within the minimum two-year period or to reduce the pass-through payment for an individual drug to zero, yet this is precisely what CMS has done in the final rule. These actions are in direct conflict with Congress' intent in enacting the transitional pass-through system in the first place—to ensure that Medicare beneficiaries had access to innovative drugs, biologicals, and new technologies.

The rule asserts that Aranesp (darbopoetin alfa ["alpha," as spelled by CMS], marketed by Amgen Inc.) and Procrit (epoetin alfa ["alpha," as spelled by CMS], marketed by Ortho Biotech, Inc.) are "functionally equivalent" because "they use the same biological mechanism to produce the same clinical result." CMS goes on to state that "because darbepoetin alpha has two additional carbohydrate side-chains, it is not structurally identical to epoetin alpha. However, the two products are functionally equivalent: in this case, both products use the same biological mechanism to produce the same clinical result, stimulation of the bone marrow to produce red blood cells. Thus, Epogen®, Procrit™, and Aranesp™ are all functionally equivalent."

Ortho Biotech's Procrit is marketed in some 80 countries worldwide, with annual sales of $2 billion. In clinical trials in various anemic patient populations, Procrit has been shown to effectively increase and maintain hematocrit and hemoglobin/oxygen and to reduce transfusion requirements.

Epogen is Amgen's recombinant human erythropoietin product. Fourth quarter 2001 combined sales of Epogen reached $609 million, a 14 percent increase from $533 million for Epogen-only sales in the fourth quarter of 2000. Full-year

payments in 2003. Because of the substantial payment reductions for drugs, more services may qualify for an outlier payment, making outliers a significant provision for hospitals providing these services. Under the final rule, the outlier payment will equal 45 percent of costs in excess of the qualifying threshold amount, or 2.75 times the APC payment amount. Therefore, qualifying for an outlier will be easier, but the payment will be less. (Currently, the outlier payment is 50 percent of the amount of costs in excess of 3.5 times the APC amount.)

As far as the overall impact to hospitals, payments to all hospitals would increase by 3.7 percent on average. Urban hospitals, however, would experience increases of

2001 sales of Epogen and Aranesp were $2.2 billion versus $2.0 billion in 2000, an increase of 10 percent.

Worldwide Aranesp sales in the fourth quarter of 2001 were $37 million and $42 million for the full year. According to Bloomberg News, some analysts estimate the market for Aranesp may be worth as much as $10 billion a year in sales.

Studies have shown that Aranesp can be taken once every two weeks compared with Procrit's once-weekly dosing. Amgen intends to use that difference to wrestle market share away from Procrit, analysts have said.

PAYMENT JUSTIFICATION

CMS established a conversion ratio to equate the doses of Procrit and Aranesp "solely for the purpose of developing a Medicare payment policy." The rule says that the ratio was based on a thorough review of the available clinical literature by CMS physicians and an independent contractor. The rule further notes that the National Cancer Institute "has been directed to work with CMS to quickly develop and sponsor a trial or trials to evaluate the appropriate conversion ratio between the two products for the purpose of Medicare pricing. …If we can estimate a more accurate conversion ratio based on this study or from our review of our own payment data, we will make a change to reflect this ratio…as soon as practicable." CMS expects this project to be completed during the development cycle of the 2004 OPPS update regulation.

For Medicare payment, each of the two drugs is assigned to its own ambulatory payment classification (APC), with the payment based on the rate for Procrit, which is 68 percent of AWP. Specifically, CMS states:

"…the products are almost identical; nevertheless there is a great disparity in their costs. In this situation, we believe it is appropriate for us to rely on our authority in section 1833(t)(2)(E) of the Social Security Act to make an adjustment we determine 'necessary to ensure equitable payments.' We do not believe it would be equitable or an efficient use of Medicare funds to pay for these two functionally equivalent products at greatly different rates. We would package these two biologicals into the same APC, but the difference in dosage metrics makes this step technically impossible if we are to maintain the ability to pay on the basis of the actual dose used. Consequently, they will be in separate APCs but paid at equivalent rates. The 2003 payment rate for non-ESRD epoetin alpha is established as $9.10 per 1000 units elsewhere in this rule. We employ the conversion ratio of 260:1 to establish the 2003 payment rate for darbepoetin alpha as $2.37 per 1 microgram. Because this payment rate equals the payment rate for epoetin alpha (albeit expressed in different units), we reduce the transitional pass-through payment for darbepoetin alpha to zero."

"…Accordingly, under this analysis, we would terminate the duration of transitional pass-through payment eligibility for darbepoetin alpha on December 31, 2002, and pay for it in a fashion comparable to other products that lose eligibility for transitional pass-through status on that date. More particularly, we would pay it equivalently to epoetin alpha."

The changes are scheduled to become effective Jan. 1, 2003.

MUCH AT STAKE

Amgen, the world's largest biotechnology company, objects to the new Medicare payment rate for Aranesp, which will be reimbursed 53 percent less in 2003 to hospital outpatient clinics. The reduction will wipe out about $63 million to $76 million of estimated 2003 Aranesp sales, said Jennifer Chao, an analyst with RBC Capital Markets, as reported in Bloomberg News. About 10 percent of Aranesp's revenue comes from U.S. hospital outpatient reimbursements.

In November 2002, Amgen filed a complaint in the United States District Court for the District of Columbia against CMS and the Department of Health and Human Services. The complaint sought an injunction prohibiting CMS from implementing certain provisions of the recently announced 2003 rule. Specifically, Amgen disputed the legality of provisions that would result in a significant reduction in the reimbursement rate for Aranesp for Medicare patients in the hospital outpatient setting, effective January 1, 2003.

On Dec. 24, 2002, the federal court dismissed the case, ruling that Amgen lacked standing in its complaint against CMS and the Department of Health and Human Services.

While members of Congress have written a letter to CMS requesting documents supporting the agency's decision on this issue, CMS has yet to respond to the lawmakers.

CMS' adoption of this "functionally equivalent" standard will deny Medicare beneficiaries access to new, innovative therapies that offer significant benefits. For patients such as ours who are battling cancer and other terminal diseases, access to these innovations could mean the difference between life and death.

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3.1 percent—less than the market basket update of 3.5 percent—compared to an increase of 6.2 percent for rural hospitals. Similarly, smaller urban hospitals (less than 200 beds) do better than larger ones (increases of 3.7 to 4.0 percent for hospitals with less than 200 beds compared to increases of 2.4 to 3.3 percent for urban hospitals with more then 200 beds). Finally, nonteaching hospitals do better than teaching institutions: 4.4 percent compared to 2.7 percent or less. The poorer showing for urban, larger, and teaching hospitals is most likely due to the changes in payments for drugs and devices.

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