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Medicare Reimbursement Changes and the Practice of Oncology: Understanding of the Past Is a Key to the Future

By Jonas A. de Souza, MD, and Gilberto de Lima Lopes Jr, MD, MBA, FAMS

The University of Chicago Medical Center, Chicago, IL; The Johns Hopkins Singapore International Medical Centre and The Johns Hopkins University School of Medicine, Baltimore, MD

In 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA); it was an event of clear historic significance for health care in America. In oncology, the PPACA has the challenging goal of reconciling the needs of a growing elderly population and the barriers to access of costly yet valuable oncologic services. To successfully bridge this gap, the oncology community must reflect on the impact that prior Medicare reimbursement changes have had on the current oncology practice model and capitalize on the lessons learned in recent years.

Medical Oncology: Complexity Toward Outpatient Care

In the past three decades, medical oncology services have shifted from being primarily inpatient (often requiring prolonged hospitalizations to deliver medications) to a nearly entirely outpatient endeavor. However, the complexity of the process has increased dramatically. There has been a steady increase in the number of drugs used to treat cancer, and most of these agents are not as easily administered as other drugs that are dispensed at a physician's office. Often, these medications are toxic, come in powder or concentrated form, and need to be reconstituted under sterile and environmentally safe conditions. Many have unique considerations that must be dealt with at delivery.

As a consequence, chemotherapy orders require a multidisciplinary professional team to execute. Orders must be reviewed by a pharmacist (or nurse in smaller practices), who then prepares the pretreatment supportive medications (antiemetics, antiallergy, and other supportive treatments) and the chemotherapy itself. These chemotherapy-certified professionals establish intravenous access and administer the medications at a specified rate of infusion within a designated amount of time (which depends on chemical stability and varies for each drug, ranging from a few minutes to a few days). Additionally, patients must be taught about the adverse effects and complications of chemotherapy. Patients are monitored during therapy, and any drug reactions must be documented. This process highlights the multidisciplinary and complex nature of cancer care.

Medicare Drug Reimbursement: From 95% of Average Wholesale Price to 106% of Average Sales Price

Reimbursement for oncology services does not reflect this complexity. The Balanced Budget Act of 1997 established that the Medicare payment for drugs would be based on either the Medicare claim or 95% of the average wholesale price, whichever is lower. Although this was originally intended to reflect the average price of medications that wholesalers sold to pharmacies, physicians, and other providers, in practice it became an index of manufacturer-reported prices and did not accurately represent the price of actual sales. This method was arguably one of the primary factors in the 25% yearly increase in payments for drugs between 1998 and 2003.[1] The Medicare Prescription Drug and Modernization Act of 2003 aimed to bring drug reimbursement closer to actual purchasing prices as well as to increase payments for drug administration. It changed the method of payment to 85% of average wholesale price in 2004 and to 106% of average sales price (ASP) in 2005 and beyond. Manufacturers are required to calculate and report to the Cen-

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ters for Medicare and Medicaid Services the ASP of their drugs, defined as the revenue generated divided by the unit sales of a drug (net of any price concessions). ASP is therefore considered a more accurate reflection of actual market prices of drugs sold by the manufacturers.

However, payments do not reflect inventory costs, bad debt, or disposal expenses. As a consequence, the business model of private oncology clinics has become increasingly dependent on the spread obtained between the cost of acquisition of chemotherapy agents and their rates of reimbursement. This has also been called "the chemotherapy concession" and has brought greater profits and scrutiny to private oncology practices. Estimates prior to the Medicare Prescription Drug and Modernization Act and actual surveys after implementation of these changes place the percentage of income derived from reimbursement from drugs between 66% and 77%.[2,3]

ASP Challenges and Implications: Nonphysician Providers, Hospital-Based, and Larger Practices

There are several problems with the use of ASP. First, there are time lags between the purchase of drugs and the price from which reimbursement is calculated. Second, because of discounts, rebates, and the bundling of products, there is a gap between manufacturers' reported ASPs and physicians' average acquisition prices. A recent example is the inclusion of prompt payment discounts—a common business practice aimed at speeding payments and taking into consideration what economists call the time value of money—in the ASP, a practice that the American Society of Clinical Oncology (ASCO) urges Congress to abolish.[4] In addition, state and local taxes are not factored in. Indeed, for many drugs, oncologists now report that they pay more than what is reimbursed by Medicare, leading to a financial loss. Finally, there is a potential conflict of interest when oncologists derive their income from prescribing antineoplastic drugs.

These challenges have forced physicians to become more efficient and see more patients to maintain the same level of income. Cost reductions have been achieved primarily by reduced drug and staffing expenses. At the same time, in view of the looming shortage of medical oncologists, nonphysician providers are increasingly and successfully having a greater role in delivering oncology care.[5] Although an increase in efficiency is a laudable economic achievement, it also has a flip side. Practices have become more selective in choosing patients, and patients without supplemental insurance are increasingly receiving treatment in hospitals rather than in free-standing cancer clinics. Given that it is harder for smaller practices to cope with these changes, there has also been a tendency for groups to merge. Indeed, the Community Oncology Alliance, a not-for-profit organization that advocates for practices, calculates that 20% of groups have curtailed their practices since 2005.[6] Moreover, physician groups have begun to look for alternative sources of income and are providing additional services, such as imaging and laboratory studies.

Pursuing Value in Reimbursement Methods: Seeing the Forest Through the Trees

The inherent conflict of interest in prescribing and profiting from oncologic drugs could raise questions regarding whether oncologists should be paid salaries rather than own hospital and medical practices. Nevertheless, one can hypothesize that physicians who have an economic interest in resale might be more likely to be thoughtful about pursuing multiple futile treatment regimens as a result of the risk of no reimbursement. Along these lines, one might also fear that salaried physicians could order whatever/whenever and be less concerned about reimbursability or value to the health care system.

We would argue, however, that the solution lies beyond the discussion of the solo/small practice versus hospital-based business models. Most medical oncologists do not maintain profit margins that might be considered abusive. For that to happen, reimbursement must reflect the value, benefits, evidence, and all of the costs discussed in this article: the actual cost of a drug, its administration and management, other cognitive services, drug wastage, inventory costs, and bad debt.

In this regard, the development of newer payment methods is essential. The bundling or episode of care payment method piloted by UnitedHealthcare in five oncology practices[7] creates a patient-care or disease management fee that is independent of the treatment regimen or drugs administered to the patient. Whether the drug is a generic or a new and expensive targeted agent, the physician are reimbursed for his/her services equally in addition to the drug cost (ASP without the 6% incentive). Other services remain paid on a fee-for-service basis. Practices are also reimbursed equally whether a terminal patient receives an active oncology drug or is under hospice/palliative care. This method clearly eliminates the conflict of interest that may occur when the physician prescribing the treatment is also the one obtaining financial benefits from the prescription of such a treatment.

The accountable care organization (ACO) concept outlined in the PPACA has the promise of integrating providers and rewarding them for restraining costs while improving quality.[8] However, the ACO concept as currently outlined has not dealt with oncology-specific issues, and none of the 65 quality measures addresses the complexities of cancer care. Actually, to incentivize the formation of ACOs, the Centers for Medicare and Medicaid Services guidelines for the Medicare Shared Savings Program has proposed rewarding ACOs that treat Medicare Part A and Part B beneficiary populations at or under a predetermined cost benchmark. ASCO's provisional opinion[9] indicates that this may create an incentive to shift cancer treatment patterns away from drugs covered by Medicare Part A and B toward Part D therapies.

Most importantly, ACOs and bundle payments do not take into account the high cost of cancer therapies. Ultimately, newer reimbursement methods will only succeed as they decrease the cost of cancer care and maintain providers' autonomy and patients' access to high-value interventions. In this regard, section 2713(c) of PPACA includes a concept that allows the

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development of guidelines to use value-based insurance designs (V-BID). V-BID strategies in oncology are founded on three principal facts: that oncology drugs may provide different benefits on the basis of their indication (eg, breast versus colorectal cancer) or the clinical scenario (eg, adjuvant versus advanced setting); that drug value, price, and patient out-of-pocket cost would be determined by the level of evidence for drug use, as well as the benefits that treatment provides; and that high-cost sharing that is based only on price discourages the use of high-value, potentially life-saving interventions, whereas high-value interventions should be promoted relative to low-value ones.[10]

Summary

Previous Medicare payment changes have led to shifts in the way oncology practices are structured. Although the PPACA allows for developing better ways to reward patient care on the basis of value and available evidence, well-intentioned changes also had unintended consequences. Understanding of the complexities of oncology care is thus key for the success of these newer reimbursement methods. We must also remember earlier lessons that showed us that any single reimbursement model is unlikely to successfully address these complexities. Bundle payments, ACOs, and V-BID tackle different aspects and flaws of the oncology business model, are not mutually exclusive, and should be developed and exist conjointly. Small, large, or hospital-based oncology practices should all be rewarded for their services on the basis of quality measures. Ultimately, high-value interventions should be incentivized and patient access to these interventions improved.

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Author Contributions

Conception and design: Jonas A. de Souza, Gilberto de Lima Lopes Jr

Financial support: Jonas A. de Souza, Gilberto de Lima Lopes Jr

Administrative support: Jonas A. de Souza, Gilberto de Lima Lopes Jr

Data analysis and interpretation: Jonas A. de Souza, Gilberto de Lima Lopes Jr

Manuscript writing: Jonas A. de Souza, Gilberto de Lima Lopes Jr

Final approval of manuscript: Jonas A. de Souza, Gilberto de Lima Lopes Jr

Corresponding author: Gilberto de Lima Lopes Jr, MD, MBA, FAMS, Johns Hopkins Singapore International Medical Centre, 11 Jalan Tan Tock Seng, Level 1, Singapore, Singapore 307743sin; e-mail: glopes@imc.jhmi.edu

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