Over 14 Years of Making A Difference In Cancer Care

Bad Medicine: Oncologists Review the Evidence Driven Drug Pricing Project's Report on the Medicare Part B Experiment

A recently released report from Memorial Sloan-Kettering Cancer Center's (MSK) Evidence Driven Drug Pricing Project (EDPP) is a clinically incoherent, agenda-driven, and dangerous analysis of oncology care and patient drug choices. This issue brief presents an examination of the "Part B Payment for Drugs in Medicare: Phase 1 of CMS' Proposed Pilot and Its Impact on Oncology Care" report by an expert review panel of practicing medical oncologists.

The quality of analysis and poor understanding of oncology care presented in this report by the MSK team is extremely disappointing. One might expect that a report from a cancer care institution such as MSK would have a plethora of experienced medical oncologists available to comment on the decision making process when formulating chemotherapy treatment plans for patients. Unfortunately, that does not seem to be the case, as none of the report's authors appear to have any significant relevant experience.

For instance, the report's lead author, Dr. Peter B. Bach, is not a medical oncologist but rather board certified in internal medicine, pulmonary medicine and critical care medicine. He does not provide chemotherapy treatment to cancer patients, and does not make the drug choices necessary to formulate treatment plans. The remaining co-authors are a hematology/oncology fellow with less than a year of clinical experience, an assistant research biostatistician, and data assistant.

There are a multitude of valid opinions on the ongoing drug pricing debate and Federal policymaking that must be considered. But first and foremost, the data upon which decisions are made must be truthful and accurate. Millions of patients with cancer in the Medicare program will be impacted by the changes proposed to the Part B program that this report is analyzing. Policymakers cannot be misled.

Drug Choices: Comparing Apples to Oranges

Clinical pathways are evidence-based treatment protocols designed to manage patient care and reduce costs without reducing the quality of care. The use of pathways is widely accepted by oncologists. Increasingly, payors are considering pathways in oncology when contracting with providers as a mechanism to improve quality, reduce variability, and decrease costs.[1]

When formulating a treatment plan, the practicing medical oncologist considers the pathways with his or her knowledge of the patient's medical and treatment history, and known drug complications and/or interactions. This includes such specifics as the patient's age, weight, comorbidities, and psychosocial considerations. This enables customized treatment protocols geared towards successfully beating the cancer while providing high quality of care and life.

To properly review the drug substitutions suggested in the report, an expert review panel of five medical oncologists on the board of the Community Oncology Alliance (COA) with a combined 86 years of experience was assembled. They evaluated the suggested pathways and drug substitutions for all factors relevant to quality of care and best outcome. Their findings were alarming.

General Findings

Rarely are two drugs interchangeable. Indications differ. Side effects differ. A patient's health, co-morbid conditions, or ability to tolerate the side effects may differ. The drug substitutions suggested in the MSK report takes little of that into consideration. They have widely differing indications and have never had any head-to-head studies published to verify equivalency.

The substitutions suggested in the report do not represent optimal or even equivalent cancer care. It appears that in making suggested drug substitutions, cost has exerted inordinate influence at the cancer patient's expense. In fact, while the drug costs may be lower, the likely costs to treat the resulting known side effects and predictable adverse events will more than surpass any savings. Coupled with the long-term detrimental effect on patient health and mortality, many of the substitutions do not represent optimal care.

Non-Small Cell Lung Cancer: Paclitaxel (Taxol) + Carboplatin versus Alimta + Cisplatin

The report suggests that paclitaxel (Taxol) and carboplatin is a comparable regimen to Alimta and cisplatin. That is absolutely not the case. First and foremost, there is no data that shows these two regimens to be equivalent. In fact, they are very different regimens with differing indications that are dependent on the type and stage of the lung cancer. The report advocates a clinically inferior treatment regimen while implying the only substantive difference is cost.

Specifically, a carboplatin and paclitaxel regimen has a high incidence of alopecia (hair loss) and neuropathy. For many patients there is a value to being able to continue life as 'normal' and without the added stressors of having to shop for a wig or be unable to drink a cup of coffee because they have lost feeling in their hands.

A cisplatin-based regimen also has a much higher toxicity and is a regimen that many cancer patients – including the elderly or those with decreased renal function, neuropathy, or hearing loss – cannot tolerate.

The estimated cost of the substitute carboplatin and paclitaxel regimen does not include the added cost of Avastin, which is typically used with this regimen to improve the results. Also, the preferred drug combination with Alimta is not cisplatin because of its much higher toxicity; an Alimta and carboplatin regimen is a safer, less toxic choice that would avoid side effects, improve quality of life, and lessen patient suffering.

Breast Cancer: Paclitaxel versus Abraxane

The report incorrectly suggests that paclitaxel is a comparable regimen to Abraxane for breast cancer. Few practicing medical oncologists would agree.

In addition to risk of severe anaphylaxis and death that can result from paclitaxel, Abraxane does not require administering pre-medications such as steroids (an issue in diabetic patients) or antihistamines (may have side-effects and impairs driving). And most importantly, there is no clinical data to establish equivalency for the substitution.

Finally, many patients with metastatic breast cancer will have already received paclitaxel in the adjuvant setting. No one would recommend re-treating a patient with paclitaxel when Abraxane has been demonstrated to be effective.

Colon Cancer: Avastin or Erbitux

The report suggests that Avastin is a comparable regimen to Erbitux for colon cancer. These drugs are not interchangeable and have completely different pharmacological elements and mechanisms of action.

Avastin blocks VEGF (vascular endothelial growth factor) receptors involved in both vasculogenesis (the formation of the circulatory system) and angiogenesis (the growth of blood vessels from pre-existing vasculature). Erbitux is a chimeric monoclonal antibody targeting EGFR (epidermal growth factor receptor).

Patients with a history of bleeding or thrombosis, recent surgery, proteinuria, or severe hypertension are not able to receive Avastin. Other patients may not be candidates for Erbitux because it can cause severe diarrhea, KRAS mutation status, and dermatological problems.

Of course, all of this is moot because patients who are candidates for Erbitux will often eventually require treatment with Avastin. By treating with both drugs patients have an additional treatment option they otherwise would not, thus increasing their chances of survival.

Cost of Care Differentials Between Settings: Community Oncology, Hospital Outpatient Departments, and PPS–Exempt Cancer Hospitals

Most cancer patients are treated in one of three settings. The majority, almost 70%[2] are treated in an office-based, or community oncology, setting. Another approximately 20% of patients are treated in community and teaching hospital outpatient departments (HOPD) based cancer centers. The remaining patients are treated in one of the 11 prospective payment systems (PPS)-Exempt Cancer Hospitals, also known as PCHs.

The cost of cancer care can vary substantially depending on the type of facility in which a patient is treated. The cost of care in the community oncology setting is the lowest and the highest in PPS–Exempt Cancer Hospitals. It is important to note that while criticizing community oncology where the cost of care is most efficient, Dr. Bach and his colleagues are at MSK, one of the PPS–Exempt Cancer Hospitals where the cost of care is higher and less efficient.

Multiple studies confirm that chemotherapy in the community oncology setting, regardless of drug choice, has a significantly lower cost than the same care when provided in a hospital-based setting. The Moran Company confirms that on a per-beneficiary basis, hospital chemotherapy administration spending was 42% higher in 2009, 67.8% higher in 2010, and 51.1% higher in 2011 than physician office chemotherapy administration spending.[3] A recent report by the actuarial firm Milliman found that hospital outpatient department costs for chemotherapy per-episode and per-session were 28% to 53% higher than the same treatment provided in the community oncology setting.[4]

A recent GAO study found that because Medicare reimburses PPS–Exempt Cancer Hospitals based on their costs, they have little incentive for efficiency and can actually increase profits by increasing the cost of care.[5] The GAO recommended that Medicare should consider paying these hospitals – including MSK – the same it pays other hospitals to encourage efficiency and avoid overspending.[6]

This point is well made in the MSK report in Figure 2 on Page 6 which shows that payments to community oncology practices are less than half those made to hospitals, including both 340B and non-340B facilities. Yet, paradoxically, the report fails to mention the tremendous cost savings community oncology presents to the U.S. health care system.

ASP + 6%: It's Not "Profit"

Currently Medicare reimburses providers at the Average Sales Price plus 6% (ASP + 6%). Since 2013, sequestration has further reduced that to 4.3%. The fundamental premise of the report states "That bill [for chemotherapy] has two parts: a reimbursement based on the average price of the drug, and a percentage based mark-up, or profit."

The 6% is not and never has been a "profit." The Centers for Medicare and Medicaid Services (CMS) does not describe the 6% as profit. The characterization by the report of the 6% as profit is wrong and biases the flawed conclusions that are the substance of entire the report.

In fact, Dr. Ezekiel J. Emanuel, a noted oncologist and bio-ethicist, commented in a New York Times Opinion, Aug. 8, 2011, "The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA 2003) … required Medicare to pay the physicians who prescribed the drugs based on a drug's actual average selling price, plus 6 percent for handling."

The 6% is intended to cover the costs associated with things such as the purchase, storage, administration, and disposal of toxic chemotherapy drugs. For many practices today, the 6% does not fully cover the cost of administering chemotherapy drugs. For many drugs, the acquisition cost is higher than the reimbursement due to wholesale discounts not passed on to providers and the sequestration deduction.

What Do Oncology Practices Use ASP + 6% For? Not profit.

The 6% is not profit, but rather covers services required for the safe delivery of chemotherapy not covered by existing reimbursement systems. This includes:

- Chemotherapy drug refrigeration and storage
- Drug mixing and preparation, including equipment, staff, and supplies
- Disposal of toxic chemotherapy waste.
- Treatment area staffing, in many cases including a portion of the cost of an oncology nurse, and equipment
- Cognitive services that are needed such as nutrition services and most general social work/advocate services
- Treatment planning and counseling
- Care coordination
- Supportive care, palliative, and end of life care
- Financial counseling

Providers are underwater on the drugs themselves before any of the related expenses. For all drugs, even those for which the acquisition cost is covered, the handling fee covers some but not all of the costs associated with providing chemotherapy. Oncologists rely on marginal revenue from drug payments to make up the difference. Thus, drastic reductions in the drug payments jeopardize the ability of oncologists to deliver the therapies.[7]

It should be noted that expenses related to chemotherapy not covered by the 6% were to be reimbursed through the establishment of CPT billing codes promised following implementation of MMA 2003. Today, 13 years later, many of these codes still have not been established. This leaves providers with no mechanism to bill for services rendered in the course of chemotherapy and its related activities. Providers must therefore rely on the 6% to cover all associated expenses.

In 2010, COA worked collaboratively with Avalere Health to design and administer a detailed survey to identify the complete suite of services performed by community oncology practices and to capture detailed costs associated with all aspects of delivering high quality cancer care. When comparing the difference in current Medicare reimbursements to practice costs, Avalere found that the practices sampled would receive payment equivalent to 56.53% of the costs they incurred to provide infusion services.[8]

The implication by the MSK report notwithstanding, drug reimbursement at a rate of ASP plus 4.3% cannot be construed as "profit" when more than 56% of the costs of the services associated with providing chemotherapy are not reimbursed at all.

Summary

Dr. Siddhartha Mukherjee, author of the 2011 Pulitzer Prize winning book, *The Emperor of All Maladies: A Biography of Cancer*, comments on the motivation and contribution of community oncologists in this manner, ". . . community oncologists are really the frontline of cancer medicine. I have enormous respect for community oncologists because much more than oncologists at tertiary care centers, they see the full range and breadth of the disease. When I was [working] in Boston, the one person's judgment who I trusted almost universally was the very first oncologist that the patient often saw, and this often was a community oncologist. They had a real sense of what was happening not only medically to the person, but also socially, emotionally, and so forth, and made a very valuable ally in treating a patient."[9]

Many of the newest cancer drugs, which currently have no alternative, have achieved unprecedented survival rates and advanced the state of patient care. Inevitably, advances in cancer care will collide with the cost of new drugs – innovation leads to new drugs that often come with higher costs. The high cost of oncology is an issue that must to be addressed by industry, providers, patients, and policymakers. However, to simply avoid drugs that are proven to save lives simply as a means to control costs is an unethical violation of the Hippocratic oath, which physicians have sworn to uphold.

While probably well intentioned, this MSK report is fundamentally flawed because it is based on the faulty premise that physicians put profits over patient care. There is absolutely no evidence to suggest that community oncologists select drugs based on profit rather than on patient care. There is ample evidence to suggest that by evaluating patient status, potential side effects, and presumed outcomes, community oncologists consistently base drug selection on quality of care. To imply otherwise is an affront to the thousands of oncologists, oncology nurses, and affiliated cancer care professionals in America, of which Dr. Bach and his colleagues are most certainly not.

---

[1] Journal of the National Comprehensive Cancer Network; Equity in Cancer Care: Pathways, Protocols, and Guidelines; Jessica K. DeMartino, PhD, Jonathan K. Larsen, MPP; Volume 10, Supplement 1; October 2012.
[2] Community Oncology Alliance; 2016. Berkeley Research Group; Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration; June 2014.
[3] The Moran Company; Cost Differences in Cancer Care Across Settings; August 2013.
[4] Milliman; Comparing Episode of Cancer Care costs in Different Settings: An Actuarial Analysis of Patients Receiving Chemotherapy; August 2013.
[5] Unites States Government Accountability Office; Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency; February 2015.
[6] Ibid.
[7] Journal of Oncology Practice; The Long Battle Over Payment for Oncology Services in the Office Setting; Joseph S. Bailes, MD, Terry S. Coleman, JD; January 2014
[8] Avalere Health; Providing High Quality Care in Community Oncology Practices/An Assessment of Infusion Services and Their Associated Costs; February 2010.
[9] Oncology Nursing News; Interview with Siddhartha Mukherjee, Author of The Emperor of All Maladies; Christin Melton; March 4, 2011.