

Healthcare Reform: Oncology PAP Program Design in the Age of the Federally Insured

By Coline David

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA) into law. The stated aim of the law is to provide comprehensive health insurance reforms that will hold insurance companies more accountable, lower healthcare costs, guarantee more healthcare choices, and enhance the quality of healthcare for all Americans. Key provisions to take effect over the next four years include expanding Medicaid eligibility, subsidizing insurance premiums, giving incentives for businesses to provide healthcare benefits, prohibiting denial of coverage/claims based on preexisting conditions, establishing health insurance exchanges, and offering support for medical research. Elements of these provisions are funded by pharmaceutical manufacturers in the form of fees and mandatory discounts on products sold to Medicare beneficiaries.

With respect to oncology drug access, the most significant components of the reform include the filling of the Medicare donut hole—with a 50% discount from pharmaceutical companies on oral oncologics covered under the Part D benefit—and the prohibition of denials for cancer treatment based on preexisting conditions (Table 1).

Overall, healthcare reform has positive aspects for drug manufacturers. It is set up to protect innovative therapies, provide limitations on discounts to 340B hospitals and facilities; and with the expanded coverage provided for the uninsured, annual U.S. drug sales could increase by \$9B to \$12B or 3% to 4%. Additionally, there is a financial disincentive for generic switching in the donut hole, generating higher levels of brand loyalty among patients and providers¹.

Despite these positives, healthcare reform creates some legal and accounting quagmires with respect to manufacturers' patient access program (PAP) designs specifically related to the tax treatment of the 50% rebate pharma companies must pay on all branded drugs that fall in the Medicare Part D donut hole. While discretionary charitable contributions to independent 501(c)3 organizations receive favorable tax treatment, the obligatory rebate to Medicare Part D does not. Instead, the rebate acts as an excise tax. Furthermore, this rebate is effectively a cash contribution and is significantly more costly to pharma than cash-in-kind contributions. Other legal and accounting issues relate to characterization of patient coverage mix, an increasingly complex exercise as government subsidies to commercially insured patients muddy the waters on who is considered "federally insured" and thereby ineligible for certain manufacturer PAP programs.

Table 1. Filling the Medicare Donut Hole

2010	<ul style="list-style-type: none"> • \$250 for all seniors who hit the donut hole
2011–perpetuity	<ul style="list-style-type: none"> • 50% discount to seniors on all Medicare Part D brand name drugs; does not apply to generics
2011–2020	<ul style="list-style-type: none"> • For brands, coverage in the donut hole ramps up from 0% to 25%. By 2020, pharma pays 50%, plans pay 25%, and beneficiaries pay 25% • For generics, coverage through the donut hole ramps up from 0% to 75%; the consumer pays the remaining 25%

Source: Kantar Health, Oncology Market Access-US 2010

Affordability Issues for the Insured

Although the vast healthcare reforms will provide millions of Americans with access to care, the issue of affordability does not completely disappear. Many insured patients will still need financial assistance to cover insurance co-pays, coinsurances, premiums and deductibles. Because of these obli-

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for the manufacturer who must offer deep pricing discounts to certain hospitals that take indigent patients.

According to our survey, availability and ease of accessing funding is rated among oncologists as the most important foundation attributes (Fig. 2). Enrollment in a foundation happens on a monthly basis and is extremely labor intensive for practices. Typically, on the first day of every month practices call foundations to enroll patients in programs, but often “if you don’t get through within the first 20 minutes the phone lines are open, the foundations run out of money.” A 2009 study on foundation cancer co-pay support conducted by Wilshire Oncology Medical Group,² found the practice burden of obtaining foundation funds to be high, with administrative costs at approximately \$264 per patient or \$75 per application (3.5 applications per patient). The study also identified the average interval

between the submission and approval of the application to be 20 days. Many practices cannot wait that long to administer a treatment to a patient so they send the patient to a hospital for the first several cycles. Then, take the patient back when and if the foundation grants are obtained.

To ease practice burden, manufacturers may wish to consider disease-specific funds that support all the financial components of a drug regimen (e.g., pre-treatment drugs, therapeutic drugs, supportive care drugs, service fees, etc.), and not just their drug. If a second drug in a regimen has no co-pay assistance support via a foundation, then it doesn’t matter how beneficial foundation coverage is for the first drug. The patient still won’t be able to afford his/her entire regimen, and the outcome of this situation is negative for all stakeholders (the treatment is changed, or the patient is sent to the hospital). One practice

administrator stated that “the more drugs in a regimen, the more likely we are to send the patient to the hospital because we don’t want to deal with multiple foundations for a single regimen... too complex. If they are only getting one drug (eg, Herceptin, Rituxan), it is worth the effort.”

Practices identify which foundation to call either from communications with the company’s sales representative or via the company/product website or PAP hotline. Manufacturers launching a new tumor fund with a foundation should contact pertinent patient support groups, medical societies, and other interested organizations and issue a broad communication/press release. **KM**

Importance of Cancer Foundation Attributes, 2010

Distribution of 100 points

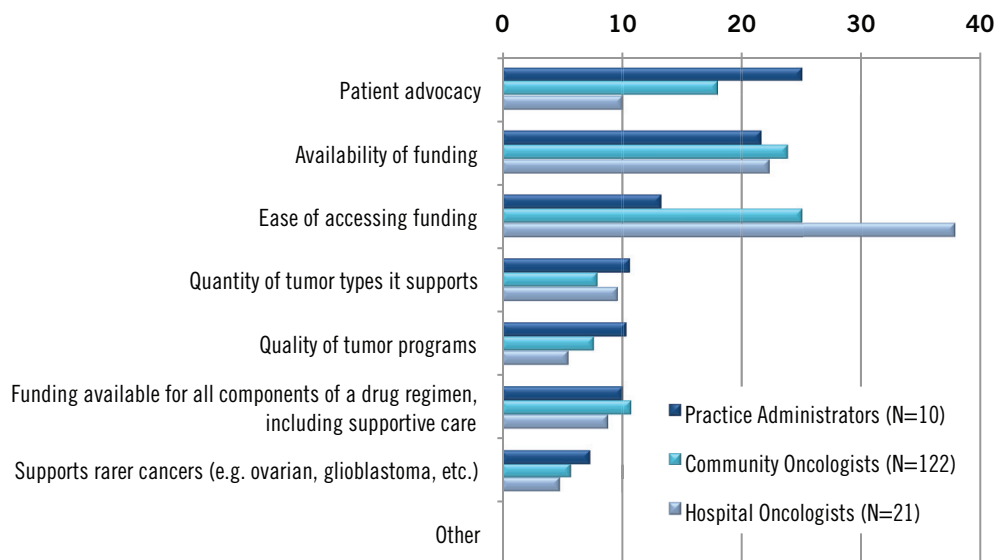


Figure 2. Source: Kantar Health, Oncology Market Access-US 2010

About the Contributors of This Article

KANTAR HEALTH

Kantar Health, a global consultancy and marketing insights organization, delivers value to our clients in the life sciences industry through four globally integrated practice areas: Treatment Value, Commercial Development, Brand and Stakeholder Management, and Marketing Insights. Formed in 2009 by uniting Consumer Health Sciences, Mattson Jack, TNS Healthcare, and Ziment, Kantar Health is the next-generation decision-support, delivering evidence-based guidance to accelerate clients’ global and local success.

To learn more about how Kantar Health can address your business challenges, please contact us at info@kantardealth.com or visit our website at <http://www.kantardealth.com>.



Key Points

What is the best way to redefine and redesign your PAP to address the changes brought about by healthcare reform?

- First, anticipate the growing need for cost-sharing support in the federally insured segment at the expense of the uninsured and commercially insured segments due to healthcare reform.
- Second, factor in an increase in PAP program costs associated with cash support rather than product support for the expanding federally insured segment and for the Medicare rebate. Be flexible for “gray areas” in coverage mix, where it is unclear whether a portion of the patient population qualifies as commercial or federal. Build a cushion for additional cash requirements associated with these gray areas. Most PAP costs range between 1% and 4% of gross sales (a \$500M drug might have a \$5M program).
- Third, design “oncology practice friendly” programs with consideration toward practice workflow and the administrative burden of enrolling patients in programs. As manufacturers change their program eligibility criteria based on new insurance paradigms, oncology practices are simultaneously trying to establish more and more patients as eligible for assistance. Limit practice guesswork and frustration by having seamless PAP triage services.
- Finally and most importantly, manufacturers need to continue funding PAPs—it’s a lose-lose situation for all stakeholders if the patient gets treatment in the hospital.

1. Meckler L, Mundy A. For drug makers, concessions have a bright side. *Wall Street Journal*. June 23, 2009.

2. Rajurkar SP, Presant C, Bosserman L, McNatt W, Wilshire Oncology Medical Group Inc. A novel co-pay assistance support program for patients receiving IV cancer therapy in cancer centers. *J Clin Oncol*. 2009;27:15s(suppl; abstr 6630).

» OBR DAILY NEWS FLASH

Is two months more of life with Herceptin®, Genentech’s drug just approved for HER2-positive metastatic stomach cancer, worth its hefty price of \$4,200 (per month)? (*San Francisco Business Times*, 10/22/10)

AACR (Philadelphia, Pa.)

William S. Dalton, MD, PhD, CEO of the H. Lee Moffitt Cancer Center in Tampa, Fla. and Chair of the Science Policy and Legislative Affairs Committee of the American Association for Cancer Research (AACR), was honored with the 2010 Leadership in Personalized Medicine Award from the Personalized Medicine Coalition at the Harvard Personalized Medicine Conference on November 17 in Boston, Mass. **Napoleone Ferrara, MD**, a member of the AACR since 2000, was the recipient of the 2010 Lasker-DeBakey Clinical Medical Research Award. Dr. Ferrara, a native of Italy, is a fellow at Genentech specializing in tumor biology and angiogenesis. He was honored for his discovery that vascular endothelial growth factor (VEGF) is a major mediator of angiogenesis, and for developing an effective anti-VEGF therapy for wet macular degeneration, a leading cause of blindness in the elderly.

ACCC (Rockville, Md.)

David S. Alberts, MD, Director of the Arizona Cancer Center, received the 2010 Clinical Research Award from the Association of Community Cancer Centers (ACCC) at the 27th National Oncology Economics Conference in St. Louis, Missouri. Dr. Alberts is Regents Professor of Medicine, Pharmacology, Nutritional Science, and Public Health at the University of Arizona College of Medicine in Tucson.

BRISTOL-MYERS SQUIBB Co. (Princeton, N.J.)

Bristol-Myers Squibb Company and Otsuka Pharmaceutical Co., Ltd. launched My Sprycel® Support, a resource to assist adult patients with chronic myeloid leukemia (CML) who are taking the medication. The patient-centric program supports appropriate medication management; offers access to a 24/7 patient call center and a Sprycel Care Counselor; and provides co-pay assistance for eligible enrollees. Patients interested in learning more about My Sprycel Support can call 1-877-526-7334 or visit www.SPRYCEL.com.

DENDREON Corp. (Seattle, Wash.)

Ian Clark, CEO of Roche’s U.S.-based Genentech unit, resigned from Dendreon’s Board after serving less than a year as a director. Clark said in a statement that his current job responsibilities at Genentech limited the time he could devote to being an effective director. Dendreon inked a development and supply deal with Glaxo-SmithKline for Provenge®, which runs through December 31, 2015. The agreement covers the commercial production and supply of the antigen used in the manufacture of the prostate cancer vaccine.

ESMO (Milan, Italy)

The 35th European Society for Medical Oncology (ESMO) Congress proved to be a milestone event for the Society and was the biggest, and best congress ever, according to **ESMO President David J. Kerr**. Over 13,000 medical oncologists alone attended the global meeting.

FOX CHASE CANCER CENTER (Philadelphia, Pa.)

Barbara Pro, MD, joined Fox Chase as an Attending Physician in the Department of Medical Oncology. Dr. Pro treats patients with Hodgkin and non-Hodgkin lymphomas, specializing in T-cell lymphoma. She had been an Associate Professor in the Department of Lymphoma/Myeloma, Division of Cancer Medicine at the University of Texas MD Anderson Cancer Center in Houston.

GE HEALTHCARE (Aliso Viejo, Calif.)

General Electric Co.’s healthcare unit agreed to buy Clariant, Inc., in a deal that values the company at about \$580 million, to speed up its expansion into cancer diagnostics tools as incidence of the disease increases. The transaction is expected to close in late 2010 or early 2011.

THE KIDNEY CANCER ASSOCIATION (Evanston, Ill.)

Nicholas Vogelzang, MD, was honored with the Eugene P. Schonfeld Award from the Kidney Cancer Association at the 9th International Kidney Cancer Symposium. Dr. Vogelzang is a medical oncologist with Comprehensive Cancer Centers of Nevada in Las Vegas. He also serves [cont. on pg 26](#) >>