

Models and Mechanisms for Assisting the Underinsured

By Tracy Foster, Dana Edwards, Morris Lumpkin, Wade Hubbard, Michelle O. Cayetano, Sara Fernandez-Lopez

A primary goal of the current U.S. healthcare reform (in both the Patient Protection and Affordable Care Act [PL 111-148] and Health Care and Education Reconciliation Act of 2010 [HR 4872]) is to help the millions of uninsured patients gain access to insurance coverage for medical care. While this goal is commendable, there is little attention, unfortunately, provided to helping the growing number of patients who are underinsured. In fact, some in congress have argued that by mandating health plans to accept anyone with pre-existing conditions—one of the core provisions in the reform—gives private plans few options but to increase patient premiums and out-of-pocket (OOP) expenses for all members in order to counter the exposure from these newly added high-risk patients.¹

Underinsured patients are in a predicament of having insurance coverage, but not being able to afford their OOP expenses associated with medical costs, and are often ineligible for assistance from such organizations as state Medicaid programs and pharmaceutical manufacturer patient assistance programs. For pharmaceutical manufacturers, designing appropriate patient support services for the underinsured can be a successful market strategy that can improve patient lives.

Defining the Underinsured and their Changing Dynamics

The definitions of underinsured vary, but in general, the underinsured includes people who are covered by insurance plans with OOP costs that exceed 10% of their household income, or that exceeds 5% of their income if that income is below 200% of the federal poverty level.² Between 2003 and 2007, this population grew 60%, from 16 million to 25 million. In addition, approximately 72 million patients under the age of 65 reported problems paying for medical bills in 2007, and 80 million reported not accessing prescribed medical care due to cost.³

Trends in insurance plans patients are purchasing show the growing number of underinsured patients. In 2008, approximately 13 million Americans had insurance coverage through individual plans (or plans that individuals can

purchase directly from insurance companies), yet 30% (or 4 million) of these patients were still likely to be underinsured in comparison to those with group plans (or plans that are sponsored by an employer).⁴ In comparison to adequately insured patients, the underinsured tend to have:⁵

- High deductibles greater than or equal to \$1,000
- Annual maximum limits
- Payer-specific limits on the number of physician visits
- Affordability issues due to noncovered benefits, and
- Nonadherence trends from skipped doses or nonfilled prescriptions due to cost

The impact of unaffordable OOP costs on care for the underinsured is critical. Over half of these patients forgo medical care despite medical necessity; and for adults with employer-group sponsored health coverage, OOP spending on healthcare increased 34% between 2004 and 2007.⁶ Approximately, 45% of underinsured experience difficulties or change lifestyles in order to pay for medical bills, and some 16% of Medicare beneficiaries reduce their medication or stop taking their medications altogether when they enter the Medicare part D donut hole.⁷ Specific to oncology, the *Journal of Managed Care Pharmacy* recently published a new study which found one in six cancer patients with high OOP costs were not filling prescriptions.⁸

Estimating the Size of the Underinsured

In order to develop strategies to support the underinsured population, pharmaceutical manufacturers will need to examine the underinsured within their target patient populations and determine how many are at risk. As there are many dynamic variables to consider when estimating the underinsured (Fig. 1), spreadsheet-based budget impact models are the usual tools of the trade.

As this article cannot address all of the key variables mentioned in the illustration, we will focus on the impact of coverage and access across the primary payer types, including a preliminary analysis of the impact of the newly approved healthcare reform.

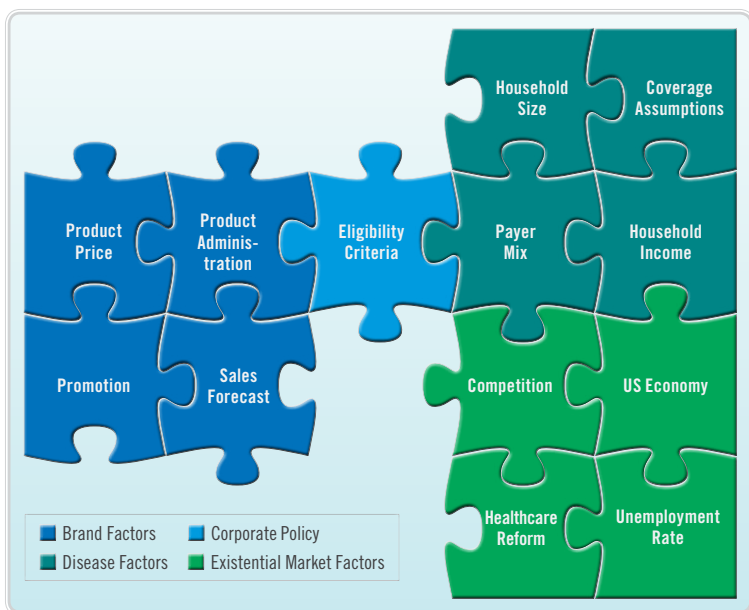


Figure 1. Underinsured Analysis Element Source: AmerisourceBergen Specialty Group. Reprinted with permission.

»» MEDICARE PARTS A & B

In the United States, some 14% of the population is covered by Medicare.⁹ When considering patients with cancer, Medicare can cover more than 60% of the population in certain cancers such as prostate, lung or colorectal.

It is important to acknowledge that Medicare Parts A and B do not provide comprehensive insurance coverage. Beneficiaries are responsible for an annual deductible and a coinsurance of 20% of allowable charges for covered services. Approximately 10% of individuals with Part B coverage do not have supplemental insurance coverage.¹⁰ The remaining 90% of patients have supplemental insurance coverage, including MediGap; but it is important to note that not all supplemental plans have nominal OOP costs. For a cancer patient undergoing IV therapy, this may mean over \$1000/month, especially when considering therapies that combine newer, more effective drugs.

»» MEDICARE PART D

Medicare Part D was implemented in 2006 and intended to enhance access to self-administered medications. Some 45.2 million Medicare beneficiaries are eligible for Part D.¹¹ While the introduction of prescription coverage for Medicare beneficiaries was a tremendous accomplishment, this benefit is far from perfect. When consider-

ing this payer type, the most important feature of Part D is the dreaded donut hole, where patients are responsible for 100% of cost until the Medicare True Out-of-Pocket (TrOOP) is met. In 2010, TrOOP is \$4,550 (\$3,610 of which corresponds to the donut hole).¹² Once that amount is met, patients will be eligible for catastrophic coverage where cost is dramatically reduced. In order to model the timing of the donut hole, one must consider concomitant medications as a patient's OOP costs for a single covered Part D drug is based on the accumulated patient OOP and drug spend of previous medications.

Medicare Part D may certainly prove to be the payer with the highest percentage of the underinsured (at least until healthcare reform is enacted to reduce the doughnut hole burden).

One of the earliest provisions to be implemented in healthcare reform would address the donut hole. Starting in 2011, manufacturers will be required to provide a 50% discount on branded drugs for beneficiaries while in the donut hole.¹³ While the implementation details have not been finalized, the intent is to reduce the patient's responsibility while in the donut hole by approximately \$1,800. The healthcare reform provisions phase out the donut hole entirely by 2020.

»» PRIVATE PAYER

Approximately 67% of the U.S. population is covered by a private health plan.¹⁴ Private payer plans consist of employment-based and individual plans, and vary significantly. In considering this payer type, primary market research with managed care decision makers could be considered the best source for coverage and benefit assumptions specific to the pharmaceutical in question. In lieu of that specific information, there are industry statistics available such as these from EMD Serono (Table 1):

Table 1: Average OOP Requirements with Private Payers¹⁵

	Copayment Range	Coinsurance Range
Pharmacy Benefit	75%	25%
Preferred	\$10 to \$50	10% to 30%
Non-preferred	\$40 to \$75	15% to 50%

cont. on pg 24 >>>

OBR ON-COMY

The *Wall Street Journal* has reported that while an estimated 70% of cancer patients under 65 have private health insurance, many have policies that cap benefits or have lifetime maximums that can leave even middle-class families vulnerable to high out-of-pocket costs.¹⁶ New healthcare reform will provide access to private insurance by prohibiting plans to deny coverage to anyone with a pre-existing condition (by 2014).¹⁷ However, no provision limits the OOP requirements of these private plans. As private payers are the second largest payer in most cancer therapies, manufacturers should continue to monitor trends in coverage of high cost therapies.

» MEDICAID

Approximately 14% of the general U.S. population is covered by Medicaid and that is now set to expand dramatically.¹⁸ Medicaid generally covers prescription medications with little or no OOP costs. However, coverage may still be limited based on utilization or other restrictions. For example, Medicaid of Texas places a 3 prescription per month limit on patients¹⁹ and Medicaid of New York has a limit of 40 prescriptions per year.²⁰ For most analyses, considering Medicaid as having little to no underinsured patients is reasonable, but for disease states with high Medicaid populations, manufacturers should consider a more in-depth analysis of at least the top Medicaid states. In 2014, healthcare reform is expected to expand Medicaid eligibility nationwide to 133% of the federal poverty level (FPL).²¹ Current projects are that health reform will expand Medicaid by another 16 million which is half of all the newly insured. This will place new urgency and pressure to ensure adequate reimbursement levels from state Medicaid programs for oncology services.²²

» SELF-PAY

It is important to note that not all self-pay patients are uninsured. Some self-pay patients have indemnity plans that typically require the patient to pay for prescription drugs up-front and then apply for 80% reimbursement. Indemnity plans account for 2% of all commercially insured patients.²³ Again given healthcare reform provisions, the percentage of cancer patients paying by self-pay should be greatly diminished.

Programs and Mechanisms to Best Serve the Underinsured

As a matter of good practice, the Amerisource Bergen Specialty Group recommends evaluating patient assistance, reimbursement support, and copay program strategies at key brand life cycle events such as initial launch, introductions of pipeline indications, increased competition and reimbursement scrutiny, as well as existential events such as fluctuations in the U.S. economy and changes in public policy such as recent healthcare reform. A range of program options and mechanisms are available for manufacturers to help close the coverage gap for their underinsured patients. The benefits of these programs include improving patient health, extending lives, and differentiating product and services from competitors. Depending on the dynamics of the target patient population a multi-pronged approach may be considered.



Figure 2. Multi-pronged Approach. Source: AmerisourceBergen Specialty Group. Reprinted with permission.

» PATIENT ASSISTANCE PROGRAM (PAF)

A patient assistance program typically provides product at little or no cost to uninsured patients. Some manufacturers have expanded these programs to assist underinsured patients either by exceptions or by policy such as



considering patients uninsured after meeting a certain OOP expense.

» DONATIONS TO COPAY ASSISTANCE CHARITIES

Copay assistance charities are 501(c)(3) organizations that are available to assist patients with OOP costs associated with specific disease-states or indications. Patients must apply for charity assistance and assistance is available based on the charitable funding. This is the only funding option currently available for federally-funded patients.

» MANUFACTURER-SPONSORED COPAY ASSISTANCE PROGRAMS

The fastest growing segment of assistance programs are manufacturer-sponsored copay assistance programs. These programs are sponsored by manufacturers to assist patients with OOP costs associated with their products. There are a variety of copay assistance program models and the primary difference is based on when the funding (or assistance) is available to the patient:

- **Pre-Pay Model:** funding is readily available to providers when services are rendered based on a pre-determined amount of funds, primarily through debit and credit cards. In this model, the funding amount is pre-determined and does not take into account the patient's specific benefits. This may require a reconciliation process to adjust assistance amounts after claims are processed through the patient's existing insurance coverage.
- **Retroactive Model:** funding is available to the patient in the form of reimbursement based documentation of the patient's cost which requires a receipt or Explanation of Benefits (EOB). In this model, patients are required to pay OOP costs up-front (or make alter-

nate arrangements with the provider) and to submit EOBs.

- **Claims-based Model:** funding is available after services are rendered through claims adjudication processes for both pharmacy and medical claims. This comprehensive model is designed to provide seamless access regardless of product distribution channels. One card for a portfolio of products alleviates the patient from additional steps to access copay assistance.

Conclusions

Given the high cost generally associated with cancer therapies, patient OOP expenses may present as the primary burden for patient access to therapy. The overlooked predicament of the underinsured may negatively impact patient health outcomes and increase overall healthcare costs. Manufacturer-sponsored patient assistance programs will ensure access to continuous care and reduce costs associated with hospitalizations when patients prolong or skip treatment. Underinsured patients should become familiar with programs that are offered by manufacturers for their therapies, as assistance may be available. Manufacturers are encouraged to complete an in-depth evaluation of the patient's needs and the gaps within various payer plans to determine the appropriate approach to close any coverage gaps. Establishing an assistance program can improve patient lives and be a successful market strategy for manufacturers. **ABSG**

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