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ORIGINAL ARTICLE

Value and payment for oncology in the United States[☆]

Valeur et paiement des médicaments innovants :
cas de l'oncologie aux États-Unis

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Summary Rather than focus on reducing prices for innovative biopharmaceuticals, insurers in the United States are changing methods of payment for oncologists in order to moderate the growth in cancer drug expenditures. The desire is for a better pattern of utilization and expenditures without adversely affecting incentives for research and development. After an overview of the contemporary discussions of price and value, this paper describes three initiatives to influence the selection and management of oncology drugs. This includes initiatives to reduce the profit margins earned by oncologists as part of the purchasing of office-infused biopharmaceuticals; “episode-of-care” payments that bundle into a single fee the reimbursement for care management and specialty drugs; and payment methods that case rates for physician care management activities with cost-based reimbursement for the oncology drugs.

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Résumé Plutôt que de chercher à réduire le prix des médicaments innovants très onéreux, les assureurs américains développent actuellement de nouvelles méthodes de paiement des médecins qui, en oncologie par exemple, visent à une meilleure utilisation clinique et à la maîtrise des coûts d'usage des produits. Après un aperçu du débat actuel sur le prix et la valeur aux États-Unis dans ce domaine, cet article décrit trois initiatives : la limitation des marges commerciales jusqu'alors réalisées par les médecins qui prescrivent et administrent ces

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Performance ;
Païement ;
Épisode de soins ;
Management des
soins

médicaments, achetés aux producteurs puis refacturés aux assureurs ; l'approche en « épisodes de soins », qui consiste en un paiement globalisé des consultations médicales, du management des soins et des traitements médicamenteux ; et enfin une troisième approche mixte, qui consiste en le paiement différencié des honoraires pour les consultations, du management par cas des soins, avec facturation séparée des médicaments sur la base de leur coût.

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Introduction

The value of a treatment, for cancer or any other condition, is the outcome achieved for the patient divided by the cost paid by society. Better value can be achieved by improving outcomes or reducing costs, or, ideally, both. Concerns for the rapid rise in oncology expenditures, and especially in the prices for new oral and infused biopharmaceuticals, is focusing attention by insurers on both sides of the Atlantic on reducing the costs incurred. Nations with universal health insurance plans, such as France and the United Kingdom, can insist on discounts off the pharmaceutical manufacturers' list prices as a condition for coverage and reimbursement. Insurers in the United States are not able to withhold coverage, and therefore lack an effective means for demanding price discounts [1]. In order to moderate the growth in expenditures, US insurers therefore focus on improving the appropriateness of use for oncology drugs, and on reducing historical patterns of over-utilization. This is done through changes in the method of payment to oncologists who prescribe and administer the drugs.

This paper begins with a brief discussion of value in oncology, and describes the possible targets for intervention. It highlights the US focus on reduction of inappropriate utilization, as distinct from reduction of unit prices. This focus stems partly from the fragmentation of the US insurer market, with neither Medicare nor the private insurers possessing the scale and capabilities to demand price reductions for targeted oncology drugs that lack equally effective therapeutic alternatives. The focus also rests, however, on a philosophic position that even low prices are too high for unnecessary treatments. Insurers do not want to pay lower prices for all uses of oncology drugs, both appropriate and inappropriate. They are willing to pay high prices for effective and appropriately used drugs, in order to reward further investments in innovation. But they want to pay nothing for ineffective drugs and for drugs prescribed for the wrong patient, in the wrong clinical setting, at the wrong dose, or with poor monitoring of patient response. The larger pressures for health care cost containment are causing a subtle shift in emphasis that might be described as a movement from "pay for performance" to "non-payment for non-performance."

A focus on appropriate utilization necessarily must incorporate the manner by which oncologists are paid for their services and the incentives they face for prescribing costly pharmaceuticals. The paper describes the perverse incentives that traditionally have faced oncologists in the United States with respect to compensation for use of office-infused chemotherapy and biopharmaceuticals. It then describes three contemporary strategies pursued by insurers to change

the methods of payment and resulting financial incentives that govern the selection and management of cancer drugs. This includes efforts to reduce the profits earned by oncologists as part of the purchasing of office-infused biopharmaceuticals; "episode-of-care" methods that pay a single rate for care management activities and the cancer drugs themselves; and blended methods of payment that combine case rates for physician care management activities with cost-based reimbursement for the cancer drugs.

Value in oncology

The value of a cancer drug is its outcome divided by its cost, but both outcome and cost are complex, multi-dimensional entities. Value-improvement initiatives thus possess multiple targets for intervention. [Box 1](#) lists the most salient ones.

The outcome of a drug derives in large part from its chemical and biological characteristics, as evidenced in randomized clinical trials and other scientific evidence presented to the FDA, EMA, and other regulatory bodies. However, the outcome of a drug treatment depends not merely on its clinical evidence, derived from studies in controlled research settings, but from the manner by which it

Box 1 Value in oncology depends on outcomes and costs, each of which offers multiple targets for value-improvement initiatives.

La valeur du traitement en oncologie dépend du résultat et des coûts, chacun s'offrant à des initiatives multiples en vue de leur optimisation.

VALUE = OUTCOMES/COSTS

Dimensions and determinants of outcomes:

- Characteristics of the drug itself:
 - safety and efficacy under ideal conditions of use;
- Characteristics of its mode of use:
 - Appropriate selection of patient and indication,
 - Appropriate choice of drug combination and pathway,
 - Appropriate monitoring: toxicity, adverse reactions, dosage,
 - Patient engagement and adherence;
- Characteristics of its global costs:
 - Drug price paid to manufacturer,
 - Price mark-ups and profit margins paid to physicians,
 - Costs of adverse side effects, especially emergency hospital visits.

is used in the real world of community-based and hospital-based care.

This includes prescription for the appropriate patient and indication, based either on FDA/EMA label or on other strong peer-reviewed and published evidence. Insurers often seek to limit reimbursement to drug uses consistent with the underlying evidence, but oncologists often prescribe drugs "off-label", outside the indications approved by the regulatory entity. This off-label use often can be valuable, since drugs cannot be tested for all indications and all patient sub-populations. But it also often can lead to over-utilization and inappropriate prescription. This can be motivated by well-meaning efforts to offer options to patients who lack on-label possibilities but also sometimes results from inappropriate financial incentives to prescribe more aggressive drug regimens or to select patients who are too frail or too advanced in their illness to benefit from the drug.

The outcome of a drug depends not merely on the choice of drug for the particular patient but on its combination with other anti-cancer drugs, supportive medications (e.g., for anemia resulting from chemotherapy and to fight infection), and non-drug treatments such as radiation and surgery. Good outcomes depend not merely on the initial prescription but on the regular monitoring of patient response, with resulting changes in dosage or drug regimen if the treatment proves ineffective, unacceptably toxic, or futile. Patient whose cancer goes into remission should be removed from aggressive drug regimens promptly, as should those whose cancer has progressed to the terminal stage where further aggressive treatment will not improve outcomes. Patients in remission should be referred back to their physician generalist while those in terminal states should be referred to palliative care.

Outcomes in oncology depend not merely on the actions of the physician but on the actions of the patient. It is important that patients and their families understand their illness and the treatment they are proposed. Ideally, they share with the oncologist the choice of treatment regimen so that their values and preferences are respected and their tolerance for risk and pain are taken into consideration. Adherence of the patient to the prescribed regimen cannot be taken for granted, especially for oral cancer drugs taken outside the physician's office. Insurers as well as physicians need to develop programs of patient education and engagement. These programs are developed and implemented most effectively by nurses and social workers with training in behaviour change rather than by physicians themselves.

Cost as well as outcome has multiple dimensions that are relevant for value-improvement efforts in oncology. The cost of a drug obviously includes its price as received by the manufacturer. The prices paid for cancer drugs have been rising rapidly in the United States, for both oral and infused products. Higher prices imply lower value for the individual patient, but can create important social value for society by rewarding investments in drug research and development.

Value-improvement can be based on pricing strategies that tailor the price for each particular drug to its clinical effectiveness. This can be very difficult to implement for administrative reasons, since clinical efficacy varies across indications, patient sub-populations, and conditions of use (as discussed above). Other components of the cost of a drug are unambiguously value-reducing. These include price

mark-ups and profit margins reaped by oncologist for purchasing and selling office-infused cancer drugs. They also include the costs of emergency department visits and hospital admissions that result from adverse side effects from chemotherapy. These visits can be reduced or avoided altogether if the patients are adequately monitored and engaged in their own care.

Incentive distortions from drug reimbursement methods

Insurers in the United States traditionally have paid oncologists on a fee-for-service basis for patient visits, plus supplemental payment for the chemotherapies and biopharmaceuticals administered in the office. Oncologists purchase the drugs from manufacturers and then claim reimbursement from insurers, in a process often referred to as "buy-and-bill." Until recently, they were able to demand reimbursement from insurers at rates substantially higher than the prices they paid to the drug manufacturers, thereby earning substantial profits off the buy-and-bill transaction. This method of reimbursement distorted the incentives facing oncologists in three ways. Fig. 1 illustrates the importance of drug mark-up profits in the United States, where they account for two-thirds of practice revenues and far outweigh insurer payments for the physicians' clinical services.

First, drug price mark-up as major source of oncology practice revenue gives the physician incentive to use the most expensive biopharmaceuticals, not to use cheaper but equally effective generic therapies. The physician's profit

Figure 1. Reliance of oncology practices in the United States on price mark-ups and profits from office-infused chemotherapy and biopharmaceuticals.

Proportion de revenu des médecins dépendant des remises et marges obtenues pour les médicaments achetés et injectés par eux-mêmes au patient.

Box 2 Physician revenues and profits from prescribing office-infused drugs are much higher for branded than for generic chemotherapies in the United States.

Les médecins oncologues américains tirent plus de revenus des médicaments princeps que des génériques qu'ils injectent.

Drug	Reimbursement ASP + 6% (\$)	Practice margin (\$)
<i>Generic cancer therapy drugs</i>		
5-FU	18	1
Irinotecan	64	4
Paclitaxel	48	3
Doxorubicin	16	1
Docetaxel	2219	126
<i>Branded cancer therapy drugs</i>		
Oxaliplatin	3699	209
Bevacizumab	2266	128
Cetuximab	2675	151
Abraxane	3062	173
Pegfilgrastim	2919	165

is greater for the most expensive drugs because the price mark-up is calculated as a percentage of the sales price paid to the manufacturer. Box 2 highlights differences in Medicare reimbursement rates for generic chemotherapies versus branded biopharmaceuticals, and the related differences in the oncologist's profit margin. Price and profit variations are much higher for privately insured patients, since private insurers lack the leverage wielded by Medicare in keeping the mark-up to only 6% above the average sales price. Oncology prescribing patterns in the US have been shown to be quite sensitive to payment incentives created by "buy-and-bill" reimbursement [2].

Second, drug price margins create incentives for physicians to increase dosages beyond recommended levels, thereby potentially endangering the patient due to the toxicity of all cancer drugs [3]. By extension, the profit margins create incentives to keep the patient on aggressive regimens even when drug effectiveness lags. Physicians should terminate aggressive treatment if the patient's condition improves and the disease goes into remission. They also should terminate treatment for patients whose conditions have worsened to the point where further treatment is futile. In these cases the patient should be transferred to palliative care rather than continue to be subjected to toxic and expensive drug treatment.

Third, high oncology price margins distort physicians' choices between use of physician-administered (infused) and patient self-administered (oral or injected) cancer drugs. In recent years, there has been a surge of oral cancer drugs that offer more convenient administration and greater patient adherence. Choice between infused and oral cancer drugs should be based on their relative efficacy, convenience, and cost, not by buy-and-bill profit incentives.

Insurer strategies: reductions in price mark-ups

In recognition of the undesirable incentives created by large drug price mark-ups, Medicare shifted in 2006 to a new system of establishing reimbursement rates. These are based on the national "average sales price" (ASP) of each drug, taking into consideration all discounts and volume-related rebates offered to any public or private purchaser. Medicare allows physicians to charge an additional 6% above the ASP to cover the administrative costs of acquiring and maintaining the drugs in the office. Many private insurers have followed Medicare's lead, though they often are forced to offer physicians 10% or 20% above ASP. Medicare subsequently reduced the administrative margin to 4% and has announced plans to reduce it further.

Reduction in buy-and-bill profits attenuated, but did not eliminate, the perverse incentives to select the most expensive drugs. The administrative supplement is calculated as a percent of the ASP, and hence rewards physicians substantially more for using high-priced biopharmaceuticals than for generic chemotherapies. Within the class of biopharmaceuticals, the ASP payment method rewards selection of drug protocols using the most expensive options. There are a large number of approved drug protocols in the United States for each major form of cancer, with wide variation in drug costs across them [4].

Pressure on buy-and-bill margins has had another undesirable effect by encouraging the shift of drug infusion from efficient community-based practices to less efficient hospital-based practices. Low drug profit margins have undermined the financial viability of independent physician practice, since these traditionally relied on drug profit margins rather than insisting on adequate payment for care management activities. This financial stress is inducing oncologists to refer their patients to hospital infusion centers. These hospital-based centers have been shown to use more of the most expensive drugs [5].

At the extreme, pressure on buy-and-bill margins, without offsetting increases in payment for care management, drives oncologists to sell their practices and accept hospital employment. Many hospitals now are seeking to employ oncologists, immunologists, and others who use specialty drugs (Advisory Board). They eye the buy-and-bill margins available from specialty drugs as a major new source of revenue. Hospitals can obtain the same ASP plus 6% payments for Medicare patients but much higher prices and profit margins for privately insured patients, compared to community-based oncology practices.

Mark-ups for specialty drugs can be particularly attractive to hospitals benefitting from designation as centers for the care of disadvantaged populations, informally referred to as "340 (B)" hospitals due to the underlying regulatory framework. Originally designed to subsidize care for uninsured patients and those covered by state Medicaid programs for the indigent, the 340 (B) program has been extended to many hospitals and clinics that primarily treat wealthy and well-insured patients. Even at safety net hospitals and clinics, the 340 (B) drug price discounts and resulting profits apply not only to indigent patients but also to those covered by private insurance and Medicare. One third of US hospitals now enjoy the 340 (B) designation. This involves

more than merely a transfer of revenue from pharmaceutical firms to hospitals. The profits further increase incentives to select drugs offering the greatest mark-up potential and to use them on more patients, at higher doses, and for longer periods of time [6].

Insurer strategies: episode-of-care payment

Bundled “episode-of-care” (EOC) payment has been developed in the United States for major surgical procedures such as knee replacement and coronary revascularization. These acute episodes of care have a well-defined beginning and end. Bundled payment combines into one fee the reimbursement for the services of the physicians, the hospital, all drugs and devices used during the admission and, in some cases, rehabilitation services after discharge from the hospital [7].

Oncology is a chronic illness, rather than an acute procedure, but has distinctive features that make it amendable to episode payment. Management of cancer is supported by clinical practice guidelines that address the most important components of care, including anti-cancer drugs, supportive treatments to help patient manage nausea, and the frequency of drug administration. Guidelines offer several potential treatment approaches from which to choose, all of which are deemed appropriate on scientific grounds but which often differ amongst themselves considerably in the drug costs incurred.

Bach et al. have described how bundled payment could be applied to cancer care based on clinical guidelines [4]. Each type of cancer would be defined as a separate episode type, for purposes of payment. For metastatic cancers, the episode would be defined as one month of care, since patients’ conditions and therefore their need for care can change rapidly. For earlier-stage cancers, such as adjuvant treatment after surgery, the episode would be longer, because care can be planned in advance with regimens ranging from 12 to 24 weeks.

Bach illustrates the potential savings from episode payment using the costs for chemotherapy, supportive drugs, and physician administrative fees for eight evidence-based care guidelines for metastatic non-small-cell lung cancer. The costs of these regimens, all of which are recommended by the authoritative National Comprehensive Cancer Network of university-based cancer hospitals, range from a low of \$1300 to a high of \$7000 per month. These costs refer to payment rates reimbursed by Medicare. Private insurers often pay much higher rates, with greater variation.

Episode-of-care payment method requires oncologists to report which clinical guidelines they are using for each patient. While doctors should follow evidence-based guidelines, insurers see frequent deviations that lack a clinical justification. Patient outcomes can be improved if oncologists adhere to guidelines, and the cost and efficacy of alternative regimens can better be assessed if all physicians are reporting their treatment choices.

Bundled payment would change the incentives facing physicians for the selection of office-infused and patient self-administered oral cancer agents. The payment rate initially could be based on the costs incurred by the physicians using whichever regimens they chose under traditional methods of payment (including buy-and-bill for the drugs

themselves and fee-for-service for professional services). Physicians would be paid the average of the costs each incurred for each type of cancer episode, including tumor type and stage of illness. They thus would benefit directly from changes in regimen towards less expensive drug combinations. The oral drugs in each regimen would be included in the episode payment along with office-infused chemotherapies.

Insurer strategies: blended methods of payment

The three principal activities performed by medical oncologists include routine patient visits for drug infusion; care planning and management outside the scope of routine visits; and purchasing of office-infused drugs. Some insurers are experimenting with blended methods of payment that reimburse office visits through fee-for-service payment, care management through monthly case rates, and office-infused drugs based on the prices actually paid to the manufacturers by the physicians.

Though often criticized as rewarding the volume rather than the value of clinical services, fee-for-service is a reasonable way to compensate oncologists for the routine office visits in which patient receive drug infusions and ancillary treatments. Fee-for-service is simple to administer and obviates the need to prospectively adjust payments according to the severity of each patient’s condition. It appropriately compensates physicians more for the care of patients who have greater needs, and less for those with fewer needs and visits.

Despite its virtues for reimbursing routine office visits, fee-for-service is a poor payment method for oncology care management. Care management involves choice among alternative treatment modalities, including surgery and radiation as well as drug regimens; patient education and monitoring for adverse side effects; and engagement of the patient’s family and community. High quality cancer care requires frequent communication to ensure that the patient understands the treatment and can differentiate symptoms that reflect the illness from those that result from the treatment itself. It is important that the patient come in as needed for adjustments in regimen and dosage, rather than allow problems to fester and lead to emergency hospital admissions. These care management activities are best reimbursed through a monthly case rate, which the oncology practice can use to pay for electronic data systems, staff devoted to patient monitoring and education, and other activities not directly linked to routine patient visits.

Neither fee-for-service for office visits nor case rates for care management is well designed to reimburse the physician for drugs administered in the office. Drug reimbursement needs to cover the prices paid by the oncologist to the distributors, plus the costs of inventory and infusion. Bundling the cost of the drugs in with professional services exposes the oncology practice to high financial risk from FDA approval of costly new treatments and to changes in patients’ conditions that require more expensive protocols. Oncologists should be reimbursed for the costs of the drugs they purchase, with the proviso that they adhere to evidence-based protocols.

A payment pilot developed by United Healthcare with five large oncology practices pays fee-for-service for office visits but adds a monthly fee for care management services, plus cost-based reimbursement for the infused drugs [8]. The drugs are reimbursed by the insurer at the level paid to the manufacturer by the physician, without price mark-ups and profits. United recognized that its traditional fee-for-service payments for office visit fees were inadequate to cover the costs of care management, and that oncologists had been subsidizing care management using drug price mark-ups [9]. The care management case rate was established at the level previously earned by the practices from drug price margins. Professional revenues to the oncology practices, consisting of the fee-for-service and case rates, did not change, but drug costs declined.

A different but compatible payment initiative was developed by WellPoint in collaboration with a major oncology practice [10]. The concept of the medical home had emerged in primary care as a means to expand the scope of care from patient visits to a more comprehensive set of activities involving non-physician staff, the patient, and the patient's family. In the WellPoint oncology medical home initiative, the insurer increases payments to the physician practice to support non-physician staffing, patient monitoring, and care coordination. The goal is to reduce adverse reactions to toxic chemotherapies through closer monitoring by nurses and social workers. The costs of the increased care management payments are to be recouped by the health plan through fewer patient visits to the hospital emergency room. Infused drugs are reimbursed to the practice at the level of price paid to the manufacturers, with a supplemental reimbursement for the infusion process. The health plan and oncology practice measure trends in these adverse effects compared to baseline rates, to ensure that increased monitoring and management do in fact result in better patient outcomes.

Conclusion

The contemporary initiatives by insurers in the US offer potential improvements in the process of selecting and monitoring use of oncology drugs, but leave several important challenges unaddressed.

First, the payment incentives for office-infused and patient self-administered oral cancer drugs remain quite different and interfere with the social goal of having selection focus on the greatest efficacy and benefit for the patient and the lowest cost for society.

Second, methods of physician payment are not coordinated with methods of consumer cost sharing and the incentives for patient adherence to oncology drugs. Cancer patients in the US often face significant co-payments and coinsurance requirements, with only partial subsidies from pharmaceutical manufacturers. Moreover, the level of cost sharing often is higher for oral and injected drugs self-administered by the patient than for infused drugs administered in the physician office or hospital-based infusion clinic. These cost sharing requirements impose financial hardship on patients, distort their choices across alternative treatments, and reduce adherence to the physicians' recommendations.

Third, the existing reimbursement methods apparently still are inadequate to sustain the viability of independent, community-based oncology practices. Oncologists continue to refer patients to expensive hospital-based infusion clinics and to switch from independent to employed status. This accelerates the consolidation of the health care industry and frustrates the larger goals of encouraging competition in a market-based system.

Finally, the contemporary initiatives do not grapple with the unit prices actually charged for infused and oral cancer drugs, but only with incentives for utilization. It is important for innovative new drugs to receive high prices, in order to reimburse expenditures on product development and the encourage further investments in research. Over time, however, the value of innovation should migrate from the producer to the consumer, in the form of declining prices. This migration is happening quite effectively for non-specialty drugs subject to competition from generic copies, but has not arrived in the US for most infused and oral biopharmaceuticals. This competition, and the resulting impact on unit prices, will only emerge when a sufficient number of therapeutically similar branded and biosimilar drugs become available for the major forms of cancer [11].

Disclosure of interest

The author declare that he has no conflicts of interest concerning this article.

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