

A Pathway Through the Bundle Jungle

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Bundled, or episode-based, payments are ingrained in the oncology reimbursement reform lexicon. Adopting these reimbursement policies in the outpatient oncology setting is appealing. Payers are able to reimburse defined, predictable payments for each patient for a set period of time, and providers have the freedom to practice medicine without being micromanaged by payers. Payers also benefit by moving away from existing policies that reward providers for doing and billing more. In other words, under these reform policies, revenue centers become cost centers for providers, upending the fee-for-service paradigm.

A focus on bundled payment in outpatient oncology treatment is now of urgent concern with the announcement of the Center for Medicare and Medicaid Innovation's oncology care model (OCM).¹ The OCM incorporates bundled payment with a shared savings program based on spending for all care provided to patients with cancer upon the initiation of chemotherapy, inclusive of all chemotherapy and supportive care drugs (whether intravenous or oral), day surgeries, diagnostic tests, emergency department visits, and inpatient stays.

However, implementing the OCM and other bundled payment policies in real-world practice has raised a multitude of questions. Foremost among them is whether the benefits of including drugs in the bundle for practices to manage outweigh the risks? Among key opinion leaders and policymakers, the inclusion of drugs in an

outpatient oncology bundle seems a foregone conclusion.¹⁻³ Both the prices of these drugs and their use pose challenges to the system; launch prices for new, branded drugs are high and have grown on average 12% per year since 1995,⁴ outpacing spending growth on cancer care more generally and overall medical care. Overuse and misuse of these drugs also likely account for a nontrivial amount of spending levels and trends.

Policymakers tout the benefits of including all drugs in bundled payment policy for the following reasons. First, physicians, rather than patients, are the ones who control demand because insurer coverage and payment for novel drugs used on and off label are virtually guaranteed⁵ because patients are generally well insured at the margin via Medigap policies and/or are covered by charity organizations. Second, practices generate substantial revenue from drugs covered under the insured patient's medical benefits because of the buy and bill system.⁶ If oncologists are at financial risk for the drugs they choose to use to treat patients with cancer, then they will be more likely to choose the least costly regimens when efficacies are similar; this will mitigate spending growth and promote the use of generic and biosimilar drugs when available. Third, because oncologists will become more price sensitive under these payment policies, they will seek out better prices for the drugs they use to treat patients through negotiations with manufacturers and other parties in the drug distribution chain.



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Although compelling in theory, there are significant risks for outpatient oncology practices entailed in including drugs in bundled payment reform. On the basis of a review of economic theory and empirical evidence, we argue that although drugs may represent the most rapidly growing cost component of cancer care, their costs are neither the most readily controllable nor the largest component of variability in cancer care spending. We then review the practical difficulties of including drug costs in a bundled payment policy for practices. We propose an alternative hybrid payment policy for managing drug-related spending that retains bundled payment for most care elements but manages drug use and associated spending using pathways.

Economics of Bundled Payment Policies

Conceptually, bundled payments aim to transfer risk associated with high levels of spending from payers to providers. The risks associated with outpatient cancer care spending are composed of the following two components: probability and technical. Probability risk is the classic form of risk that people buy insurance to mitigate and involves random or unpredictable events. In oncology, probability risk is related to the spending required to address the random event of a patient getting a particular cancer and seeking treatment from a specific practice. Technical risk is related to the practices' clinical skill and efficient management of diagnosis and treatment or other aspects of care that are under the physicians' control. In theory, bundled payments should only transfer the components of spending risk from payers to providers that the latter can control (ie, technical risk). Responsibility for spending components outside of providers' direct control (ie, probability risk) should be retained by insurers.

On the basis of this, one way to evaluate whether oncology bundled payment policies should include drug spending is to examine what components of spending risk community oncology practices can control at a given point in time. Spending on drugs can be divided into two parts, prices and quantities.

The empirical evidence on whether drug pricing is a probability or technical risk for practices is limited. For two reasons, we believe the prices of new cancer drugs should be considered a probability risk for oncology practices, rather than a technical risk that they have the power to control.

First, one often-quoted example of drug prices being a technical risk practices can control is the example of ziv-aflibercept (Zaltrap; Sanofi, Paris, France).⁷ Soon after Sanofi's August 2012 launch of the biologic drug into the US market, its

price triggered a public act of defiance on the part of oncologists.⁸ Physicians from Memorial Sloan Kettering Cancer Center said in a *New York Times* op-ed piece^{8a} that they would not prescribe the drug because it cost twice as much as bevacizumab (Avastin; Genentech, South San Francisco, CA), a competing biologic drug with similar expected clinical outcomes for patients with colorectal cancer. In response, Sanofi said they would reduce the price of the drug by 50%. Before the discount was offered to purchasers, average per-person costs for treatment with ziv-aflibercept amounted to \$11,407 in 2014 US dollars (USD).

Whether this example will extend to price-setting practices among branded manufacturers of other new drugs is unknown at this time, but we have reason to be skeptical. Policymaker and public media scrutiny of drug prices has been intense since the ziv-aflibercept story broke, and oncologists have increasingly publicly decried the high pricing of cancer drugs.⁹⁻¹¹ However, evaluating average monthly launch prices of cancer drugs during this period tells a different story. Between 2013 and the first quarter of 2015, 27 new oncology drugs have entered the US market.¹² The average per-person monthly cost of treatment with these drugs launched between 2013 and 2015 amounted to 2014 USD \$13,415 ($n = 27$; standard deviation, USD \$11,228); the average per-person monthly cost of treatment with cancer drugs launched between 2010 and 2012 amounted to 2014 USD \$14,141 ($n = 19$; standard deviation, USD \$10,208). There is no statistical difference between these average launch prices (t test with unequal variances, $P = .82$). Thus, even in the face of increased physician awareness and stakeholder scrutiny, manufacturers have not pursued moderating pricing strategies.

Our second concern is related to the locus of control over drug-pricing negotiations. Among infused and injected chemotherapy and supportive care drugs covered under insured patients' medical benefits, practices may have some leverage over the acquisition prices of generics and drugs with competitors in a therapeutic class. Their leverage comes from 340B drug discounts limited to the entities that qualify for the program and/or the volume of drug purchasing they are pursuing in a given period of time. These discounts are not passed through to payers or patients but retained by providers. The latter pricing leverage does not come from the practices themselves, but rather the purchasing power of the group purchasing organizations they belong to and is likely confined to drugs that do not provide significant gains in efficacy or effectiveness over alternative therapies and/or existing therapeutic alternatives. Oncology practices have no control over

the prices paid for novel and existing oral drugs covered under the pharmacy benefits of patients with cancer because these prices are negotiated by payers or on the behalf of their payers by pharmacy benefit managers.⁶

Oncology practices do have some control over how many lines of therapy they use, which regimens they choose, and off-label use. Consequently, we believe the use aspect of drug spending should be considered a technical risk. Previous evidence suggests that off-label use without obvious clinical support amounts to approximately 20% to 30% of annual spending on these drugs, although it varies considerably by drug¹³ and by practice type.¹⁴ Some of this use is driven by the paucity of evidence supporting treatment of some patients and/or missing data, and some of this use is driven by the lack of therapeutic treatment alternatives. The justification for including drugs in bundled payment focuses on this technical risk; supporters of bundled payment are implicitly arguing that it is exactly these uses for which spending is wasted and should be eliminated. The following questions remain: What should this care be replaced with, and what are the patient outcome and cost implications of this practice change? On these issues, the empirical evidence is sparse.

From a broader vantage point, we doubt that outpatient oncology bundled payment policies that are inclusive of drugs are the most efficient focus of a policy change given the magnitude of potential savings from drugs relative to other care components. Our skepticism derives from studies quantifying regional variation in spending on cancer care components. Brooks et al¹⁵ analyzed fee-for-service Medicare data and reported that only 10% of regional variation in spending is from chemotherapy drugs despite these drugs composing 16% of total spending. The rationale to focus on chemotherapy drug spending is diminished when you compare this to the 67% of regional variation in spending related to acute hospital care spending, which accounted for 48% of total spending.¹⁵ Certainly more study is warranted, but this suggests that chemotherapy drug use is not a significant source of spending variation when examined at an aggregate market level.

A real-life example of the principles of probability and technical risks may have played out in a recently reported United Health Care demonstration project. Despite the replacement of a margin on average sales price with a management fee designed to remove the potential for profit by using more expensive therapies, drug costs increased. Nevertheless, the demonstration was hailed a success because shared savings and bundled inpatient evaluation and management services led

to decreased hospital and emergency department utilization.¹⁶ Our interpretation of the counterintuitive result is that the probability risks associated with drug costs could not be controlled by participating practices but the technical risks associated with hospital and emergency department services were. The United Health Care data ultimately support the motif of this editorial that despite establishing tight control of drug regimens in the episodes of care, costs are not predictable, thereby conveying substantial risk to the community practice if drugs are included in a bundle.

On the basis of this review, bundled payments in oncology that include chemotherapy may have limited impact on the prices of individual drugs but a potentially large impact on their use. This view is also consistent with the fact that established bundled reimbursement in other medical specialties such as end-stage renal disease and cardiac care has largely targeted spending related to the quantities of inpatient care, diagnostic tests used, and delivery of additional supportive care services.¹⁷

Potential Unintended Consequences of Outpatient Oncology Bundled Payment Policies That Include Drugs

Our main concern with outpatient oncology bundled payment policies that include chemotherapy and supportive care drugs is that the policies will go beyond incentivizing the most economical care to incentivizing physicians to provide less care. More specifically, there are only two ways that bundled payments that include drugs can be managed by community oncology providers; these are to define bundles with enough granularity to minimize interpatient variability or to get big (ger) through mergers and consolidation such that patient volumes are high enough to mitigate against adverse selection. The first option may not be practical, and the second is not necessarily desirable.

One way to decrease practice risk associated with drugs is to define bundles with great granularity, seeking specificity to the individual patient's disease. A system of bundled payments has little hope of keeping up with a care plan where different therapies with different costs will be required based on the molecular profile of a patient's tumor. For example, there is a group of patients with lung cancer with no driver mutations who can be treated with standard relatively inexpensive therapy such as carboplatin and paclitaxel. Conversely, there is a growing number of other patients with lung cancer whose tumors have driver mutations such as *EGFR*, *ALK*, *ROS1*, *MET*, *RAF*, and *HER2* or who have inducible immunogenic

tumor environments who will require expensive therapy and who may be on these therapies for a long period of time because of their effectiveness. Just 4 years ago, Bach et al² could propose an episode-based payment for lung cancer based on four equally efficacious therapies for a monolithic cancer. To make this suggestion today would be problematic as a result of innovation.

It is naïve to assume that any system will be granular enough to risk-adjust payments to oncologists based on interpatient variability or the presence of outliers. It also is naïve to assume that any payment system will be nimble enough to adapt to the rapidly changing world of precision medicine. It is little wonder that in their first effort at a bundled payment policy, United Health Care and The University of Texas MD Anderson Cancer Center have chosen head and neck cancer, a disease in which drug therapy and choices are limited, and yet even then, they have developed eight distinct treatment/payment bundles.¹⁸

Because of the impracticality of managing rapidly changing granularity, it is anticipated that bundles will be relatively generic. High volumes of patients will be needed to manage the inescapable interpatient variability within a given bundle. Consolidation of practices, via mergers, acquisition, or affiliation with health systems, will allow practices to increase patient volumes, improve buying power, and increase their ability to negotiate with payers. Although this may be acceptable to health policymakers, payment policies that change the incentives for how providers organize themselves may have important unintended consequences. For example, there is limited evidence that consolidated provider practices improve the quality of patient care and/or increase patient access to care.

One way to surmount these concerns would be to remove drugs from the outpatient oncology payment bundle. In effect, this would remove the challenges associated with managing drug price and use in the bundle but leave in place incentives to lower costs that are within the reach of the oncology provider, such as diagnostics, imaging, emergency department services, and hospital use. This leaves the main objection to leaving drugs out of an outpatient oncology bundled payment policy, which is that it incents practices to (perversely) rely on drug-based treatments because they are off-budget.

Incorporating Clinical Pathways In Alternative Payment Models

If drugs are not included in the bundle, how might payers be assured that they will be properly used? We believe that a promising strategy to mitigate both the technical and probability

risks of drug spending lies in the use of oncology treatment pathways. Specifically, payers could pursue a hybrid approach by keeping evaluation and management visits, hospital stays, emergency department visits, and diagnostic testing in the bundle and incorporating pathways to manage drug spending.

Pathways impact physician behavior through the provision of directed evidence-based clinical decision support designed to improve value, quality, and safety. This is often achieved through transparent, peer-reviewed, committee-selected treatment choices that incorporate efficacy, toxicity, and cost considerations. This reduces variance in drug regimens, drug doses, drug schedules, and treatment duration and may improve patient safety. Exceptions to pathways are expected but provide an opportunity to focus on variances that are worthy of detailed attention, improving pathway compliance over time. As pathway development matures, these tools will incorporate more sophisticated value models to account for the total costs incurred by a given treatment regimen inclusive of toxicity costs, use of ancillary support services, and patient productivity loss. Indeed, such information would be anticipated to dramatically support clinical decisions and affect outcomes that are meaningful to patients and payers. Several studies have shown savings achieved with what might be considered rudimentary pathways and less than stellar pathway compliance.^{19,20}

Recently presented data on the cost of biologics in metastatic colon cancer illustrate how a value pathway might work. In the Cancer and Leukemia Group B/Southwest Oncology Group 80405 study, the two arms of chemotherapy plus bevacizumab versus chemotherapy plus cetuximab were equivalent for efficacy and toxicity, but cetuximab costs \$40,000 more than bevacizumab.^{20,21} A value-based pathway would encourage the use of bevacizumab. Practice governance or payers could provide incentives or disincentives for deviating from the pathway more than a certain percentage of time (usually set at 20%). The program requires documentation for any patient treated off pathway. This has the advantage of explicitly showing how cost is being considered while at the same time allowing practices reasonable variation for patients in whom cetuximab may be preferred (eg, a patient with significant vascular risk factors or uncontrolled hypertension). A bundle inclusive of drugs would hide the cost pressures on oncologists and could actually incentivize the use of no biologics or the inappropriate use of bevacizumab. In contrast, the pathway incents the use of the more cost-effective regimen but does not penalize for use of the more expensive therapy if appropriate. The pathway process prospectively captures

exception data, allowing for the practice and payer to understand why the pathway algorithm did not apply. Under either the bundle that includes drugs or pathways, the pharmaceutical industry would be incentivized to bring the price of the biologics closer to parity, although one might argue that the transparency in a pathway further increases downward pressure on price that is hidden within a bundle.

Several demonstration projects have shown that use of treatment guidelines, quality measurement systems, shared decision-making tools, and redesign of care processes can reduce spending on drugs, tests, and imaging as well as reduce avoidable complications and improve the quality of care for patients. For example, in one project involving more than 1,400 patients with lung cancer across the United States, the use of evidence-based treatment guidelines was found to reduce 12-month average costs for chemotherapy by 37% (\$6,923) and average costs for other medications by 39% (\$2,824); total spending for patient care was reduced by 35% (\$9,695 per patient).¹⁹ In a project involving more than 4,700 patients with cancer at more than 46 sites, drug costs were found to be 13% lower (\$2,440 per patient) at sites adhering to clinical pathways than sites that were not adherent.²⁰

Through explicit and transparent control of drug utilization based on efficacy, toxicity, and costs, pathways achieve many of the beneficial goals sought with bundled payment. In addition, including costs in the selection criteria of preferred regimens should put downward pressure on prices. This will not solve the problem of prohibitively high launch prices for effective drugs with limited competition; that problem will persist under any proposed payment system in the United States short of direct price controls. However, when there is competition between therapies, which is an increasing probability given the current robust pipeline of drug-based therapies, competition for placement in a pathway will depend on competitive pricing, including the offer of discounts and rebates.

In conclusion, placing cancer drugs in an outpatient oncology payment bundle may well mitigate cost variability for payers; however, this is accomplished by putting both providers and patients at risk. Bundled payment policies can and should be used to manage variation between practices and spending associated with the technical risks of care, including diagnostic imaging, molecular diagnostics, emergency department visits, hospitalizations, and inappropriate end-of-life care. We believe provider-driven pathways may be more effective at incentivizing the use of the most effective, least toxic, and most cost-effective drug regimens, while still

allowing providers enough flexibility to practice the art of medicine. Indeed, if robust provider-driven pathways are used, bundled payment policies that include drugs are unnecessary. Coupling bundles with provider-developed drug-based pathway systems would seem an optimal way to leverage payment reform to incent appropriate behaviors and control costs, which is a win-win-win for the payers, providers, and patients. **JOP**

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