Duke | Robert J. Margolis, MD Center for Health Policy

Exploring approaches for value-based reimbursement of oncology therapies

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Backgrounder

Introduction

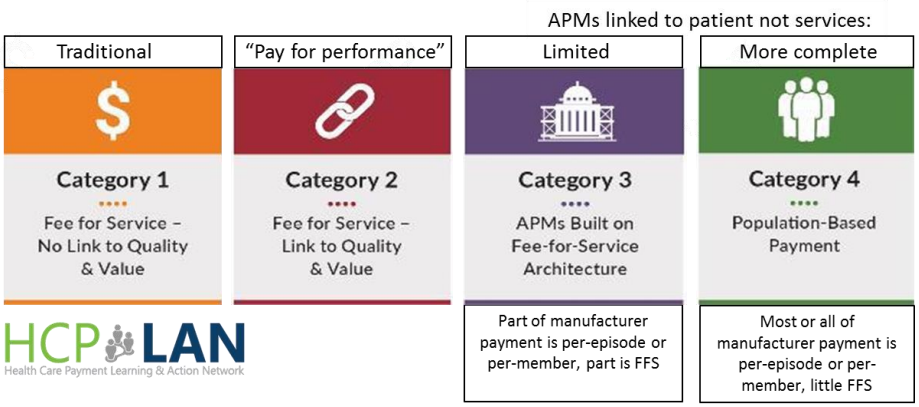
Advances in cancer care over the last thirty years have resulted in improved outcomes for patients.[1] Between 1970 and 2000, the five-year breast cancer survival rate increased from 75% to 90% and the one-year lung cancer survival rate increased from 34% to 45%; overall, the cancer death rate in the United States (US) dropped 13% between 2004 and 2013.[2-5] More recently, new immunotherapies have offered better outcomes for particularly challenging cancers, including late stage melanoma.[1] However, with these advances, spending has risen dramatically. In the US, cancer care accounts for nearly 30% of healthcare costs, totaling $87.8 billion in 2014.[6-8] Furthermore, while the rate of increase in specialty drug prices in the US has slowed, spending continues to increase, with oncology treatments as the second and third highest reimbursed therapies in Medicare and commercial insurance, respectively.[9] The proliferation of targeted immunotherapies and other expensive, innovative mechanisms of action (e.g., Chimeric Antigen Receptor (CAR) T-Cell Therapy) signal that cancer care spending trends are not likely to improve in the near future. At the same time, care is becoming more complicated, and the type of treatment that will be successful may not be the same for each patient. As a result, payment and reimbursement of care and therapy in the oncology space have been changing in the past few years to emphasize value and patient outcomes.[10,11] Specifically, payers are engaging with providers to implement value-based care through alternative payment models (APMs), including episodic payments to help curb cost and optimize outcomes. Payers are also partnering with manufacturers to implement novel payment strategies that reward effectiveness, such as outcomes-based agreements and indication-based pricing. However, cancer drugs have yet to be fully incorporated into comprehensive value-based arrangements.

The Duke-Robert J. Margolis, MD Center for Health Policy, supported by a grant from Eli Lilly & Co., is convening an expert workshop to explore approaches for value-based reimbursement of oncology therapies. The goal of this workshop is to identify steps to enhance the success of value-based payment models for cancer care, with an emphasis on payments to drug manufacturers that better align with provider alternative payment approaches, aiming to improve outcomes and avoid inefficient and low-value spending for cancer patients. To support this work, this landscape assessment reviews publicly available information on oncology value-based models implemented in the US to date, and identifies common themes and challenges across models. This work will align with broader efforts at the Duke-Margolis Center for Health Policy aimed at addressing key practical issues in advancing value-based payment (VBP) arrangements for health care providers, pharmaceuticals, medical devices, and transformative therapies.[12]

Framework for Alternative Payment Models

Overall, the US healthcare system is transforming how it pays for care by implementing APMs that emphasize quality and outcomes over volume of services. The HCP-LAN APM framework was developed to "track progress toward payment reform," and categorizes payment and reimbursement models based on the level or financial risk ranging from fee-for-service (FFS) to global payments (Figure 1).[11]

Figure 1: Payment categories defined by HCP-LAN



Within the HCP LAN framework, Category 1 is the traditional FFS model, without a link to quality or value.[11] For example, physician administered products are typically reimbursed at the cost of the product plus a percentage of the cost of the product to cover administration and the provider's time (e.g., in Medicare this is average sales price (ASP) + 6% of ASP). As a result, clinicians and health systems have an opportunity for a greater return by using higher priced drugs. This "buy and bill" structure creates a perverse incentive to use higher priced products regardless of their relative value,[13] and this type of model can incentivize high volume use of healthcare services, which can increase the cost of health care.

Category 2 models link FFS to measures of quality and value, but retain a FFS structure. For example, in 2015 the Medicare Access and CHIP Reauthorization Act (MACRA) was implemented. It includes the Quality Payment Program (QPP), which physicians may fulfill through two options. The first is by participating in the Merit-based Incentive Payment System (MIPS), which builds on the Affordable Care Act's efforts to shift provider reimbursement from FFS to care quality performance in Medicare by tracking performance quality data and adjusting payments based on performance.[14-16] The second way is through provider participation in an APM, and oncologists are developing APM programs specific to them. Under MACRA, most oncologists will be paid under MIPS for their Medicare beneficiaries, with their payment rates adjusted by a composite performance score based on measures related to processes of care, information technology capability, and other aspects of quality. Preliminary models may also provide additional payments (typically paid per episode or per member per month (PMPM)) for developing the infrastructure expected to be necessary for high-value care that may not be otherwise reimbursed, including care coordination or "oncology medical home" capabilities.[11]

In contrast, Category 3 and Category 4 models represent lesser or greater shifts away from a FFS structure. Category 3 models retain FFS payments, but also include a component of reimbursement tied to quality and cost of care at a condition, episode, or patient-level for an accountable population of patients.[11,14] For example, the CMMI Oncology Care Model pilot program includes measures of quality as well as utilization for episodes of cancer care starting with the initial use of chemotherapy, and private insurers have also implemented models that tie payments to utilization and quality for accountable populations. These include both shared-savings and limited shared-risk models, in which providers can receive additional payments if patient utilization and/or spending are lower than a benchmark while still meeting quality performance benchmarks. In category 4 models, population-based payments are mainly tied to the episode or patient (e.g., a fixed bundled payment, or partial or full capitation, with quality performance requirements). Providers, including physicians and healthcare systems, bear greater levels

of financial risk in these more advanced APMs, but they also have greater flexibility to redirect resources to new care models. These APMs also provide support for delivering higher-quality care than is feasible under FFS payments, and can receive greater financial support for care models that are effective in improving patient outcomes and lowering costs.

There is considerable evidence that many important aspects of effective care models are not reimbursed well under FFS payments in cancer care – for example, care planning, team-based care, after-hours access to services in ambulatory clinics that could head off emergency department visits, more efficient planning and use of imaging services, palliative services, and the use of evidence-based treatment regimens matched to a patient's genetic profile and preferences. Consequently, a diversity of reforms have been implemented to transition health systems to models that create stronger incentives and support for higher value in care. Many APMs have multiple elements, and as a result, models do not fit neatly into the categories described above. Moreover, with limited experience, and many such models being at the pilot phase, they are continuing to evolve based on experience with the models in practice and with evolving provider capabilities to succeed.

Oncology Payment and Delivery Reforms

There is growing interest in oncology-specific APMs that build on and begin to move away from a fee-for-service infrastructure. This section focuses on oncology payment reforms targeting providers through APMs, which have taken a number of forms. Below, examples of the most common approaches are discussed, including initiatives that use quality reporting, clinical pathways, bundled payments, and accountable care organizations. A full list of examples identified by this landscape assessment can be found in Appendix Table A.

QUALITY REPORTING

Quality measures are a fundamental component of value-based APMs because of the step-wise transitive nature of their implementation - from simply reporting to measuring performance. The American Society of Clinical Oncology (ASCO)'s COME HOME initiative provides one example of a cancer-specific program that utilizes quality reporting to build upon a medical home arrangement.[17,18] COME HOME was tested through a CMMI-funded pilot project in seven community oncology practices across Medicare, Medicaid, and commercial insurers. This program is an oncology-focused, patient-centered medical home that incorporates CMS quality reporting requirements. In addition to quality reporting, key initiatives include improving care coordination between physicians' offices and hospitals, expanding office hours, implementing standardized data collection, and developing and implementing clinical and triage pathways[19] The program demonstrated successes in the initial pilot, including a reduction in hospital readmission, emergency department and inpatient hospital visits. The pilot also demonstrated an overall reduction in care costs.[18,20] As a result, ASCO has recently partnered with Innovative Oncology Business Solutions, the original developers of COME HOME, to expand the program.[18]

CLINICAL PATHWAYS

Clinical pathways are a recommended treatment plan based on a patient's presentation and disease stage that steer providers toward more cost-effective medications. Clinical pathways can reduce care variation and tie clinical oncology pathway compliance to payment.[13,21] Bonus payment incentives and non-compliance penalties can be used to encourage physician participation; physicians can avoid being penalized by following a pre-defined, optimal treatment pathway at a designated threshold of compliance.[22,23] There may also be an opportunity for physicians and healthcare systems to share in the savings or loss generated through these pathways, so both physicians and payers can benefit from these

arrangements. These types of arrangements can be attractive to physicians because of consistent payment, reduced paperwork related to utilization review, and the potential of better patient outcomes, while payers gain predictability and increased use of high-value care.[13,22] Clinical pathways can also bring a greater understanding of different treatment options and their associated costs to all stakeholders including payers, providers, and patients.[13,22,23] However, clinical pathways can also have some drawbacks, including clinician disagreement with the particular pathway for a patient, limited evidence for treatment, and additional administrative burden.

Clinical pathways can have a range of structures. Single-option pathways have one treatment protocol that is assigned to a single episode of care for a particular group of patients. [22,23] In multi-option pathways, two or more treatment protocols would be considered compliant for an episode of care. To reduce time burden on physicians, pathways are often implemented and evaluated by third-party administrators such as AIM Specialty Health or Eviti.[23] While clinical pathways have gained traction after the passage of the 2003 Medicare Modernization Act, a 2012 survey of nearly 50 payers (representing regional and national plans and 100 million lives) found that only 39% had implemented oncology pathways; however, among those who had not, 59% were planning to do so.[21,22]

An early adopter of the clinical pathway payment model was BlueCross BlueShield of Michigan (BCBSM). In 2010, BCBSM sponsored a pathway program in breast, colon, lung, lymphoma, myeloma, ovarian, and prostate cancers for Oncology Physician Resource (OPR), the Michigan Society of Hematology and Oncology's practice management organization.[22-24] While BCBSM sponsored the pathway development and maintenance (including quarterly updates), participating physicians created the pathways. For adjuvant and metastatic treatment, the adherence threshold was set to 70% in the first year and 80% in subsequent years, which ensured that physicians had adequate leeway for individual treatment decisions for unique patients. BCBSM used three incentives to gain physician participation. First, to ease administrative and workflow hurdles, physicians received a $5,000 payment for participation. Second, to encourage generic product use and remove perverse incentives of reimbursing at average sale prices, the reimbursement rate for generic products was increased. Third, BCBSM shared potential savings in chemotherapy and supportive care with the provider. A third stakeholder, the benefit manager Cardinal Health, oversaw the implementation and evaluation of the pathway, which was measured using claims data. At the end of two years, the program experienced a 44% decrease in branded chemotherapy payments.[25] This program had other successes including: 1) high provider participation (95% at the end of year 1); 2) reduced chemotherapy variation; 3) increased generic use (when the brand regimen of choice was equally effective and toxic), 4) increased use of less expensive brand regimens (when the brand regimen of choice was equally effective and toxic), and 5) improved limited later-line therapy use. These and other positive, value-based care trends led to reductions in emergency room and hospital visits.[22-24]

Early pathway programs, such as that implemented by BCBSM and OPR, focused on specific cancers and patients, and were primarily implemented at the practice level. Today, oncology pathways are more generalized and are implemented more broadly.[25] For example, Anthem's Cancer Care Quality Program (CCQP), managed and implemented by AIM Specialty Health, has developed, and frequently updates, evidence-based pathways "that are intended to be applicable for 80-90% of individuals with the most commons cancer types."[26] This program is structured to reward compliant providers with a care management fee, and providers are able to share clinical data with the payer through a registry, which includes tumor type, stage, therapy line, biomarkers, planned treatment, and performance status, to help track quality and outcomes.[25,27-29] Additionally, due to advances in technology, providers are able to submit their treatment plans online with automated, real-time compliance monitoring and reporting.

[23,30] This program was applicable to both Anthem's commercial and Medicare Advantage plans and was rolled out in 13 states by 2015.[31]

Bundled and Episodic Payments

With episodic payments or bundled payments, a benchmark price is assigned to an episode of care spanning different care sites and providers.[32] Utilizing the fee-for-service infrastructure, the evaluation of services provided against the set price threshold can be either retrospective or prospective (e.g., capitation or global payment). For example, the Centers for Medicare and Medicaid Services (CMS) Medicare Oncology Care Model (OCM) is a retrospective, episodic payment demonstration project, in which an episode starts on the chemotherapy initiation date (Part B or Part D) and includes all Medicare Part A and Part B fee-for-service reimbursements, and some Part D expenditures. In this program, physicians receive a Monthly Enhanced Oncology Services (MEOS) payment of $160 and are evaluated every six months against a benchmark for an additional bonus payment.[33,34] If the physician or provider group agrees to share in the risk of spending more than an agreed upon benchmark, the bonus incentives for reduced spending are larger. In order to account for new therapies that come on the market, target prices, which are calculated based on risk-adjusted benchmarks and the Medicare Trust Fund discount, can include a novel therapy adjustment, when relevant.[33-35] There are several requirements for participating in this model, including: 1) enhanced services (patient navigation, care plan containing the Institute of Medicine's components, real-time access to providers 24/7, and guideline-concordant care), 2) data-driven quality improvement, and 3) certified EHR technology.[33,34,36] In addition, there is a quality measure-reporting requirement, including Communication and Care Coordination, Person and Caregiver-Centered Experience and Outcomes, Clinical Quality of Care, and Patient Safety, though only 12 of these quality measures are used in the performance calculation. Importantly, the OCM is a multi-payer model in which commercial plans may also participate so long as they align with CMS's requirements, including a focus on patients receiving chemotherapy, enhanced service and performance payments, data sharing participation, and quality measure alignment.[36] Currently, 190 practices and 16 payers are participating in the OCM, including integrated delivery networks.[34]

UnitedHealth Group (UHG) initiated a chemotherapy-centered, prospective episodic payment pilot with five oncology practices. This contract included 19 defined episodes across breast, colon, and lung cancers.[13,37,38] To participate in the model, oncologists committed to adhering to a clinician-defined, evidence-based optimal treatment regimen for each episode 85% of the time. When chemotherapy is used in an episode, rather than receiving reimbursement at ASP plus a contracted percentage such as 6% of ASP, providers received a fixed payment on top of the ASP. The fixed payment included 1) the drug margin, or the difference between the price the physician is typically reimbursed and the average sales price of the treatment regimen, and 2) a small case management fee.[13,37,38] The purpose of this episodic fee was to remove the incentive to select higher priced drugs and to cover physician hospital care (FFS), hospice management (may be covered FFS), and case management (not covered under FFS). Notably, UHG has created a national cancer registry, from which control patients were identified. Surprisingly, despite being targeted, chemotherapy costs increased by over 175% compared to the predicted costs ($7.5M) during the study time frame; however, overall medical costs decreased by $33M.[13,37,38]

Building on this pilot, UHG has initiated new bundled-payment collaborations. For example in 2014, UHG and MD Anderson partnered to develop eight prospective bundled payments in patients with newly diagnosed head and neck cancer.[39] Notably, these two entities worked together to create bundles that were responsive to physicians' feedback during the implementation process, for example, by mitigating

provider risk through inclusion of a stop-loss provision and incorporating the inclusion of new, expensive therapies into bundles.[40] UHG has also launched a similar bundled payment system with the Moffitt Cancer Center for lung cancer.[41] Other examples of payers partnering with providers on bundled payments include 1) Anthem Blue Cross of California and Valley Radiotherapy Associates Medical Group for breast cancer and 2) Highmark, Allegheny Health Network, and Johns Hopkins Kimmel Cancer Center for cancers treated with mediation and radiation for breast cancer.[42,43] Details of these agreements can be found in Appendix Table A.

Accountable Care Organizations

Accountable care organizations (ACOs) control costs by making providers accountable for the total cost of care across a given population, with either upside or downside risk determined through evaluation against a benchmark. The benchmark measurements of ACOs are not assigned based on a single episode of care; instead, they are based on the population of interest across care sites and providers. The first publicly announced cancer-specific ACO was between an oncology practice, hospital group, and regional payer (Advanced Medical Specialties, Baptist Health South Florida, and Florida Blue, respectively).[44] Two hundred and twenty-six cancer patients were included in the ACO in the first year based on a cancer diagnosis and three evaluation and management visits.[45-47] The three stakeholders share savings greater than 2% as long as quality metrics are met. Quality measures include those required by CMS, Baptist Hospital, and US Oncology, of which Advanced Medical Specialties is part.[48] This ACO has been highly successfully to date, with nearly $9,000 in savings per patient in the third year of the program. Sources of savings include improved chemotherapy and supportive therapy pathway adherence, decreased emergency department visits, and improved end-of-life planning.[45,46] In addition to this ACO with Advanced Medical Specialties and Baptist Health, Florida Blue has also created a cancer-specific ACO with Moffitt Cancer Center.[49]

Value-based payment models for drugs

In this section, novel payment arrangements intended to link payments to observed or expected value in a population are reviewed. These models incentivize better value and outcomes, and involve agreements between manufacturers and payers, including PBMs. In these models, drug purchasing by providers and reimbursement to providers are not involved.

Indication-based pricing and other proposals to increase transparency have the goal of tightening the link between the price per use of a product to existing evidence of effectiveness and potential value. They use the FFS reimbursement system, and do not tie payment to actual observed outcomes. Indication-specific pricing approaches typically review the available evidence on the impact of a drug on key health outcomes and possible dimensions of cost or utilization, and they apply a value framework to that evidence to determine a range of appropriate drug prices. ICER's Value Assessment Framework and estimates of "value-based" indication-specific cancer drug prices by Drug Abacus developed by Bach and colleagues are examples of this approach.[50-52] While indication-based pricing in the US is still in its infancy, CVS and Express Scripts have recently announced the initiation of such programs.[53,54]

Other models that focus on moving away from FFS and addressing uncertainty in outcomes and performance link total payments for a medical product to actual results or outcomes observed in the population using the medical product. These **outcomes-based contracts** are negotiated between payers and manufacturers linking payment for medical products to that product's real world performance, with the goal of better aligning payment with the outcomes achieved for patients. Such models can involve sharing outcome- and total spending-related performance risks among the parties involved in use, principally between manufacturers and payers, but may also include, providers and (at least for shared

savings) potentially consumers. Accountability for results is based on measures that can include clinical or patient-reported outcomes, utilization outcomes, measures of spending, and/or quality of care measures.[55] Although the terminology associated with these types of agreements can vary (as "risk-sharing agreements," "outcomes-based agreements," "performance-based agreements," or other terms), these arrangements share a common feature of linking payment for therapies or interventions to outcomes achieved.

Yet, current measures are imperfect and the experience of providers and manufacturers in aligning with payers to improve outcomes is limited. As with payment reforms for health care providers, which mostly represent limited shifts away from FFS toward results-based payment, implementation of these arrangements might be meaningfully viewed on a spectrum or pathway. Initial contracts are likely to represent only a limited departure from traditional FFS. As experience and capacities to implement such payment reforms increases, contracts could move toward tighter, direct alignment with actual value produced for patients and the health system in real world settings. Limited approaches include manufacturer "warranties" that involve full upfront payment, with rebates provided back to payers based on whether an agreed-upon performance measure is achieved. While incremental steps will be needed to achieve, approaches that are more comprehensive would not only involve value-based pricing such as indication-specific pricing, but also link total payments to a more complete set of measures of clinical outcomes as well as total cost of care, and thus more fully aligning with the impact of the medical product on value in the treated populations.

These latter arrangements potentially allow all involved parties, including payers, manufacturers, providers, and health systems, to align their financial stakes directly with the performance of the medical product encouraging greater shared efforts to improve outcomes for the patient population treated. While most arrangements are negotiated directly between payers and medical product manufacturers, there is increasing interest in manufacturer-provider arrangements with the proliferation of alternative payment models, including ACOs and other APMs reviewed above.

Publicly available information on VBP in oncology is limited. However, there have been four publicly announced drug-specific agreements: a Novartis-CMS agreement for Kymriah (tisagenlecleucel), a Genentech-Priority Health agreement for Avastin (bevacizumab), an AstraZeneca–Express Scripts agreement for Iressa (gefitinib), and a CVS Caremark Transform Oncology Value program that has an agreement with undisclosed products used in non-small cell lung cancer (NSCLC) and breast cancer.[56-58] In August 2017, the US Food and Drug Administration (FDA) approved the first gene therapy, tisagenlecleucel in certain pediatric and young adult patients with a form of acute lymphoblastic leukemia, a population where limited treatment options exist. While priced at $475,000 per treatment, CMS will only reimburse Novartis if patients respond within the first month of treatment.[59] For Avastin, the agreement was for Genentech to rebate Priority Health an amount inversely proportional to the length of progression-free survival (PFS), up to six months for first-line use in NSCLC.[56] This outcome, the median of a key endpoint, was measured at the individual level to expedite the measurement and rebate process. Reasons for discontinuation prior to six months were categorized as disease progression or toxicity, which were rebate-eligible, or patient/provider preference, which was rebate-ineligible. Impressively, to get information that was not provided by their claims data, Priority Health put forth significant effort to assess discontinuation reasons through a combination of EHR data accessible through a regional health information exchange and physicians' offices as well as other physician records. For successful pilot implementation, all stakeholders had to agree to certain assumptions for practical reasons such as identifying eligible patients based solely on diagnosis codes, which does not provide information on staging, though the indication is specifically for stage four NSCLC.[56] For Iressa,

AstraZeneca reimbursed the full costs of the drug to Express Scripts, a pharmacy benefit manager, if the patient did not respond and discontinued the medication prior to the third fill. The intention of the agreement was to promote adherence and optimize medication effectiveness to achieve value.[58] For CVS Caremark, outcomes will be measured through progression of disease as identified through secondary therapy use and lab data for NSCLC and cost caps (a pre-determined average cost of care threshold) for breast cancer.[57]

Challenges and Lessons Learned in Implementing Oncology Value-Based Payment Models

There are currently several challenges that impede successful VBP in oncology, which are categorized into four categories described in Figure 2. The categories include legal/regulatory, reliability, scalability, and operations/infrastructure. Below, we will explore the issues in each of these challenges as well as identify emerging lessons learned from existing value-based payment oncology models.

Figure 2. Challenges to Implementing Value-based Payment in Oncology

Legal and Regulatory	Reliability
• Anti-kickback • Coverage – Mandatory oncology product coverage • Drug Pricing – Best Price in Medicaid and 340B – Average Sales Price in Medicare Part B • Off-label communication	• Varying perspectives and goals across all stakeholders – Uncertainty on degree of patient inclusion in benefits • Leadership commitment across all stakeholders • Information availability / data transparency
Scalability	**Operational/ Infrastructure**
• Administrative and set-up costs • Agreement on high value outcomes – Standardized definition of "real-world" value (clinical trial results are unrealistic) – Generalizability of outcomes across different patient populations • Sample size and timing considerations – Patient attribution	• Data collection – Missing data – Data aggregation – Data evaluation (including outcomes measurement) • Reporting and contract adjudication • Decentralized payer system (hospital/physician costs vs. PBM) – Lack of site payment neutrality – Perverse marginal revenue challenge

Legal and Regulatory Challenges

Several legal and regulatory issues pose a challenge to the successful implementation of value-based oncology payment models. First under the Anti-Kickback Statute, federal law prohibits "any exchange of remuneration (or offer of exchange of remuneration) that would incentivize the referral of business paid for by federal healthcare programs."[60,61] As such, simply engaging in components of value-based payment arrangements, such as promoting adherence and subsequently utilization, let alone discounts or rebates, could be perceived as violating the Statute.[61,62] Second, Medicare mandates anti-cancer drug coverage of FDA-approved indications, regardless of effectiveness, which does not necessarily align with high-value care.[12,61,63] Third, there are some government programs, such as the Medicaid Prescription Drug Program and 340B Program, in which prescription drug prices are based off of the best price or the quarterly lowest price for a prescription drug product (with some exceptions), including rebates and

discounts.[61] The pricing of products in value-based payment oncology models may be lower than the market's lowest price, and potentially qualify as the best price. Subsequently these government programs would receive the drugs at these lower prices, without fulfilling the other requirements of the value-based payment model. Finally, manufacturers are strictly limited in what they can communicate about products, and are primarily limited to what is on their approved product level. Section 114 of the Food and Drug Administration Modernization Act (FDAMA) allows for the health care economic information related to approved labeling to be communicated with healthcare payers.[64] Despite the recent issuance of guidance providing clarity on FDAMA 114, a great deal of uncertainty exists on what is considered appropriate communication, and whether manufacturers are able to share the information necessary to design a value-based payment model.[64] While these are important issues to address, they are not the focus of this backgrounder and expert workshop, which centers on issues that can be directly addressed by stakeholders. As such, they are thus only briefly discussed in this review. Please refer to the forthcoming Value-Based Payment Arrangements for Medical Products white paper for more information and potential solutions.[61]

Reliability

Unsurprisingly, reliability is the foundation of successfully implementing oncology value-based payment models. These models require the active participation of a combination of payers, PBMs, providers, manufacturers, and patients who all have various perspectives, expertise, and goals. All stakeholders want to improve the health of the patient, and they want to do so while minimizing their financial risk. Currently, the direct incorporation of patients' perspectives into designing models or including them as a risk-sharing stakeholder is limited. For these models to work, stakeholders must cooperate and understand their partners' needs and challenges, including patients. Furthermore, there is information asymmetry across stakeholders. Specifically, manufacturers have the most information on product effectiveness, payers and PBMs have access to claims data, and providers have access to the clinical data. Putting together all of these data sources in a reliable, verifiable way is often necessary to successfully design and implement a value-based oncology model. As value-based models are newly established, they are likely to require extensive groundwork during implementation, and leadership commitment by all stakeholders is necessary. Table 1 outlines specific examples related to reliability gathered from the landscape assessment of existing practices.

Table 1. Success Factors Related to Reliability

#	Emerging Lessons from the Field	Example
1	Collaborate with organizations in which positive partnerships already exists	• One reason UHG selected MD Anderson for the head and neck cancer episodic payment pilot because of its partnership with academics studying quality and cost of care[39]
2	Frequently communicate with partners to maintain momentum	• MD Anderson/UHG had weekly meetings to discuss emergent issues in their head and neck cancer bundles[40]
3	Share best practices across all participants	• UHG episodic payment model and OCM have meetings with all site participants to share experiences and best practices [32,34,37]
4	Solicit input from stakeholders or collaborate a third-party to develop and maintain evidence-based protocols that are transparent	• OPR offered flexibility in what was considered pathway-concordant so long as the product used was not less effective or more toxic, and more expensive[24]

5	Prevent high-cost patient shift/patient cherry-picking	• CMMI required OCM-participation by all PGPs providing care [32]
6	Foster collaboration and increase accountability between all players in a de-centralized payer system	• OCM episode expenditures spans hospital, physician, and certain drug costs increasing collaboration of all "payer" entities [32]

Scalability

Scaling value-based oncology payment models into standardized, wide-spread programs can be challenging. Oncology is a particularly difficult therapeutic area to assess and determine value because there is a large amount of heterogeneity in treatment response[10]; as result, cancer treatment often needs to be individualized. Treatment within a cancer type can vary based on stage and other factors such as biomarkers, which can be arduous to collect and track. There are also issues related to enrolling a sufficient number of patients in the model to be able to power detectable, meaningful changes; enrolling the number of patients to achieve the necessary sample size may take years, and maintaining motivation for programs over a long-period is challenging[56]. Furthermore, the composition of the patient population and risk pool, which is reflected in provider risk, varies from practice to practice. Finally, it is important to remember that providers are already responding to evolving data demands as a result of the Affordable Care Act and MACRA, including EHR implementation and quality reporting and measurement.[65] Additional data requirements or reporting requirements with high administrative burden and set-up costs can be difficult to implement by providers. Table 2 outlines examples related to scalability gathered from the landscape assessment.

Table 2. Success Factors Related to Scalability

#	Emerging Lessons from the Field	Example
1	Develop programs that are generalizable to standardize measurement and increase sample size	• Anthem Cancer Quality Pathways Program is applicable to 80-90% of patients with the most common types of cancer[26] • OCM episode use risk-adjustment in their benchmark calculation to account for different patients populations across providers[32]
2	Select methods that are simple, reliable, timely, and consistent in identifying patients and measuring outcomes	• Genentech-Priority outcomes based contract for bevacizumab used a billing code to select patient population selection and measured the outcome at the individual (versus population-level) to expedite data capture and increase rebate timeliness [56] • In OCM, an episode included the total cost of care versus only the cost of oncology-related services because of the burden to differentiate between them[32]
3	Use a short time-frame for measuring outcomes where feasible	• Genentech-Priority used a time-frame of <1 year for its VBP arrangement[56]
4	Address easy challenges (e.g., overuse of services in palliative care or supportive care)	• Pathways programs related to palliative care and chemotherapy have demonstrated success in achieving cost savings[24,37]
5	Create programs that combine value-based care with other legal/regulatory requirements	• ASCO COME Home helped reduce costs, helped implement QPP quality reporting requirements, and

laid the foundation for practice transformation toward an APM[19]

Operational/ Infrastructure

Despite the increase in oncology-specific value frameworks, there is a lack of consensus in defining high value outcomes in oncology and how they should be measured.[61] A common outcome used by manufacturers to evaluate efficacy in oncology therapies in randomized controlled trials for FDA approval is PFS.[10] However, results obtained in the controlled setting of a clinical trial are difficult to replicate in a real-world setting, and PFS cannot simply be measured in claims data. Ideally, this requires the development and implementation of a registry, which is resource intensive for payers and the providers, because it includes collecting and aggregating data from EHRs, claims data, and potentially other sources (e.g., imaging data). Even when a registry exists, evaluation can be manual and time-consuming. One option is to use proxies for PFS such as duration of therapy; however, a lack of consensus exists across stakeholders on their validity.

Oncology is a rapidly evolving field where standard-of-care constantly changes. Additionally, in the current environment, there are several targeted therapies with the same mechanism of action, which can further complicate value-based decision-making. As a result, value-based oncology payment models need to be able to consistently incorporate and address emergent, novel therapies, which again, is resource-intensive.

Several cultural and financial issues hinder the implementation of value-based payment in oncology. First, providers and payers must come to consensus on value, and consider not only their own finances but also the patient's, and the potential benefit of therapy. Second, even if the payers and providers are eager to participate they may lack the human capital (e.g., care coordinators) and infrastructure (e.g., EHRs that collect necessary data) to successfully implement these models. They are also hesitant to take on new, poorly understood financial risks. Third, physicians currently receive marginal revenue of administered products. As such, there is a perverse incentive to use more expensive products even when there is an equally effective/toxic product available. Finally, reimbursement is higher in outpatient settings affiliated with a hospital as opposed to a physician (lack of site payment neutrality), and multiple studies have shown that total cost of cancer care administered in an outpatient setting affiliated with a hospital is higher than with a provider setting.[66,67] Table 3 outlines examples related to operations/infrastructure, including flexible measurement, transparent data duration, and aligning incentives, gathered from the landscape assessment.

Table 3. Success Factors Related to Operations/Infrastructure

#	Emerging Lessons from the Field	Example
1	Select outcomes that are easy to measure and reflect the real-world	• Express Scripts – AstraZeneca VBP arrangement for Iressa used duration of therapy as a proxy for PFS[58] • Pathways use a simple yes/no concordance measure[22,23]
2	Create registries to improve patient-tracking and outcome-measurement	• OCM, UHG Episodic Care Pilot, and Anthem Cancer Care Quality Program collect clinical data through a separate registry to supplement claims data[30,32,37]
3	Maintain up-to-date evaluation standards, including new evidence, precise bundle definitions, and new therapies	• Anthem Cancer Care Quality Program updates pathways quarterly[26] • OCM has a novel therapies modifier for emergent therapies[32]

4	Reduce human capital and time resources	• Anthem Cancer Care Quality Program and Humana Oncology Quality Management Program have automated provider input systems where a provider's request is evaluated against a standard protocol for real-time evaluation[29,68]
5	Incentivize physician participation	• OCM, OPR, and UHG Episodic Care Pilot, and the Anthem Cancer Care Quality Program offered physicians up-front payment for program participation[24,29,32]
6	Mitigate provider risk	• OCM and UHG/Texas Oncology bundled payments for head and neck cancer have a stop-loss provision[32]
7	Remove perverse billing incentives	• OPR increased reimbursement of generics[24] • UHG reimbursed drugs at a standard price in its chemotherapy episodic payment pilot[37] • Commercial Oncology ACO and OCM offer shared savings/loss (site neutrality)[33,45]

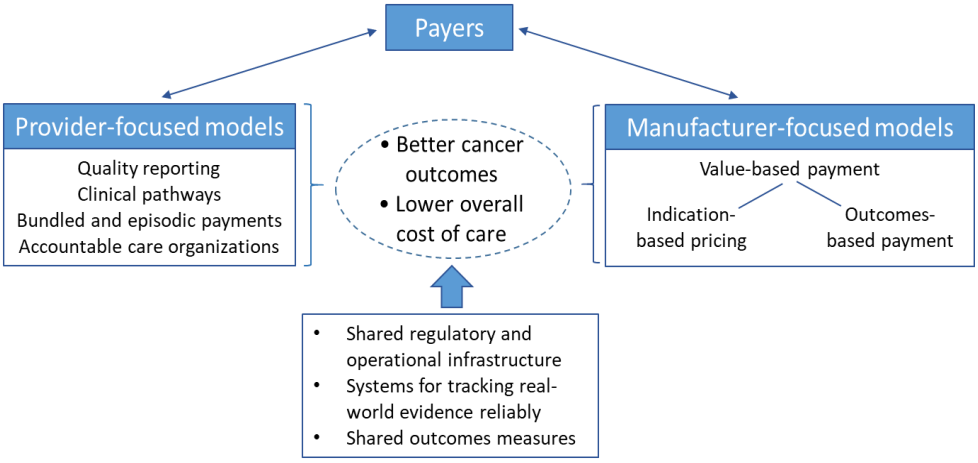
Summary of Value Based Oncology Payment Models

As described above, the types of value-based oncology payment and reimbursement models that are currently being tested in the US are diverse. This landscape analysis, which assessed both provider and drug-specific models, suggests that stakeholders combine different aspects of models when designing programs. While these models span all types of cancer, a number of programs focus on the most common cancers (e.g., NSCLC and breast cancer) as well as on chemotherapy. They contain different structures from more passive models that simply provide upfront payment for care management in patient-centered medical homes to prospective episodic/bundled payments, and they can offer opportunities for both upside and downside risk, and payments can be made prospectively or retrospectively. Incentive payments/penalties may also be rendered retroactively such as in ACOs, where performance against a pre-defined performance threshold is assessed. Value-based oncology payment models include different stakeholder arrangements, with most including a health plan payer and provider or manufacturer. However, some models may also include a PBM.

Pathways and VBP payment arrangements for medical products most directly incorporate oncology therapies as they focus on their adherence, direct outcomes, and pricing, respectively. Oncology pathways were the most commonly-reported programs, likely because they have been tested since the late 2000s and have had measurable success.[21-23] Additionally, with technology improvements, many programs today have automated compliance monitoring and evaluation programs.[30] While broader in nature, other payment models also include oncology therapies as one of many levers in achieving high-value care. For example, removing the incentive to prescribe more expensive products by inflating the cost of generics (e.g., BCBSM/OPR) or offering a flat fee on top of reimbursement (e.g., UHC original pilot).[13,24,37,38] Additionally, there are episodes of care models that focus specifically on patients receiving chemotherapy, including OCM and multiple prospective UHC bundles.[33,39,41]

As innovative care and reimbursement models become more widespread, there are additional issues that remain (Figure 3). One is how to better align the efforts of provider and drug-specific models. Payers have directly negotiated VBPs with drug manufacturers, making payment dependent on evidence of positive outcomes. These agreements do not directly involve the provider. Moving forward, it may be beneficial to find approaches that incorporate the priorities of providers in the development and implementation of VBPs for medical products, allowing for more equal distribution of benefit and risk.

Figure 3. Achieving value through payment



Another outstanding issue is how and whether the patient's financial contribution should change based on the outcomes of care. In many of these models, providers take on risk in return for shared savings opportunities. However, patients also take on financial risk through co-insurance or out-of-pocket spending, and it is important to consider whether they should share in gains or rebates based on the outcomes and quality of their care.

One of the challenges of implementing these new oncology payment models has been measuring outcomes and determining value. In the models described above, various outcomes have been used to determine quality and value of treatment, including quality and performance metric reporting, pathway adherence, and clinical and financial outcomes performance. While health insurance claims are the most common data source used to assess performance, EHRs are also commonly used. Additionally, insurer-level and provider-level registries that include clinical data not available in these sources or supplement these sources are being developed.[28,33,37] These registries may set the foundation for more complex value-based oncology payment models in the future.

For clinical outcomes, median PFS and duration of treatment have been used as a proxy for PFS; however, as new drugs come on the market, questions remain as to the amount of value that should be ascribed to extending PFS by weeks or months.[10,56,58] There is increased interest in VBPs (i.e., PFS, duration of therapy, and cost caps) and indication-based pricing in oncology and other therapeutic areas given recent public scrutiny on drug pricing. However, their mechanisms are not readily transparent. As prices for oncology drugs remain high, challenges around integration of drugs into these value-based models will need to be addressed.

Exploring approaches for value-based reimbursement of oncology therapies

In order to optimally integrate oncology drugs into value-based payment models, stakeholders must begin to define the approaches and evidence that could be used to support these new arrangements.

The Robert J. Margolis, MD Center for Health Policy at Duke University will convene a workshop to discuss the challenges and potential solutions associated with value-based payment for oncology drugs. The goal of this workshop is to identify steps to enhance the success of value-based payment models for cancer care, with an emphasis on payments to drug manufacturers that better align with provider alternative payment approaches, aiming to improve outcomes and avoid inefficient and low-value spending for cancer patients.

Session I: Promising approaches for broad implementation of alternative payment models in oncology care

Many types of APMs and value-based arrangements have been implemented for oncology care. As these types of arrangements become more common, the factors that determine success emerging, but gaps still remain. Through panelist remarks and open moderated discussion, this session will highlight the benefits, challenges, and promising approaches of alternative payment models in oncology. During this session, stakeholders will address the following questions:

- What are key challenges, specific to oncology care, to adapting alternative payment model (APM) approaches?
- Where are the emerging best practices? What might be generalizable from these case examples?
- How are clinical pathways being used to manage care and drug utilization?
- What are priorities for addressing key challenges, scaling best practices, and reimbursing for value in oncology care?

Session II: Provider – Payer APMs in Oncology: Identifying successful approaches for better integrating drugs

In response to government initiatives that emphasize value over volume of services, payer-provider contracts have made significant progress in implementing new approaches to oncology care management. However, many of these models do not directly incorporate drugs. This session will discuss how to leverage promising APM approaches to integrate drugs into the payer-provider contracts using recent value-based payment models as case studies. The following questions will be addressed during this session:

- Are there features of the agreements that could lead to better aligned incentives?
- How can these approaches best incentivize high-value drug use?
- What role can manufacturers have in supporting these payment models?
- How can patient preferences be incorporated into these models?
- What areas need more innovative thinking?

Session III: Exploring the role of manufacturers in supporting value-based approaches

Despite the increase in value-based contracts for drugs and other medical products, few arrangements have been implemented for oncology drugs. To date, payers and manufacturers have directly negotiated contracts, but with the additional financial risks that clinicians are taking on through clinical pathways, there is a need to incorporate providers into these arrangements. This session will identify promising approaches for implementing APMs between manufacturers and payers as well as discuss how manufacturers can support broader implementation of value-based care using case studies of recent contracts. This session will address the following questions:

- How can agreements between manufacturers and payers drive toward higher value care?

- Since providers who purchase the oncology medications may also be implanting APMs, what is the manufacturers' role and how can it be redefined?
- How can manufacturers share the risk that providers assume to use their products?
- What are the opportunities to align/support APMs that providers are taking on?

Session IV: Benefit design and patient perspective

Patients often pay a set out-of-pocket rate for their drugs regardless of whether the drug is reimbursed through an APM. However, as some models begin to offer rebates for drugs that do not meet performance goals, stakeholders have begun to consider how patients can share in these cost savings. This session will explore how the structure of benefit design could be impacted by value-based approaches and identify opportunities for alignment, and it aims to address the following questions:

- How can patient co-pays be aligned with value-based payment for drugs?
- How can pathways, APMs, and VBP affect patient access?

Session V: Outcomes, data, and evidence for judging real world value

Sub-session Va: Arriving at meaningful outcomes

To measure the value of a therapy, all stakeholders must agree on the most appropriate endpoint to use. However, it is often difficult to reach consensus on meaningful outcomes; those that are currently available may only be applicable to a limited set of situations. This session will discuss different types of outcomes that could be practical for oncology treatments, as well as strategies for arriving at consensus endpoints. During this session, the following questions will be addressed:

- What are common outcomes and what other types of measures should be explored?
- What are areas of disagreement on outcomes and value?
- What are strategies for working with patients to determine meaningful benefit?

Sub-session Vb: Information availability and standards

The data generated on the efficacy of drugs through clinical trials represents the best case scenario as many sources of variability have been removed. However, when therapies are used in the real world, clinical trial results are hard to replicate and the standards by which a drug is judged may be impractical. Real world data are needed to understand the value of using a drug. This sub-session will address the key aspects that will allow for the development of a robust, practical database, and stakeholders will explore the following questions:

- Who would be responsible for establishing and maintaining a real world evidence database?
- How will data be collected to enable meaningful conclusions?
- How might providers be reimbursed/incentivized for their role in data collection, drug administration, and measurement?
- How can the burden of data capture be mitigated?

Appendix A. Valued Based Oncology Pilots / Models

Model	Stakeholders	Model Type	Description	Population(s) of Interest	Data Source*	Clinical Registry*	Outcomes
Pathway Models*							
Anthem / Well-Point Cancer Care Quality Program: Clinical Pathways (managed by AIM Specialty Health)[22,23,28]	*National health plan *Specialty benefits management company *Oncology groups	Pathways Program	Physicians who concordantly prescribe with the frequently updated, evidence-based guidelines receive a care management fee of $350.	Multi cancer-intended to cover 80-90% of patients with the most common cancers	*Claims *EHR	Yes	Pathway adherence
Oncology Physician Resource (OPR) - Michigan Society of Hematology and Oncology - BlueCross BlueShield of Michigan (BCBSM) Pathways InitiativeInitiative[24]	*State health plan *Specialty benefits management company *Oncology group	Pathways Program	Physician input was used to develop pathways, where a compliance of 70% in the first year and 80% thereafter was required. BCBSM would share potential savings in chemotherapy and supportive care spends with the provider. Physicians also received $5,000 for participating in the program, and increased reimbursement for generic products.	Breast, lung, and colon cancer and supportive care using granulocyte colony-stimulating factors, erythropoietin stimulating agents, and antiemetics	*Claims		Pathway adherence

CareFirst Pathways (Managed by Cardinal Health)[22,23]	*Regional payer *Oncology groups *Specialty benefits management company	Pathways Program	Physicians who were 70% pathways compliant in the first year, and 80% in subsequent years, received higher reimbursement fees than those were not compliant.	Breast, lung, and colorectal cancers	*Claims		Pathway adherence
Humana Oncology Quality Management Program (Managed by New Centuries)[68]	"*National health plan *Specialty benefits management company *Oncology groups"		Physicians submit treatment regimens for review against evidence-based pathways; non-approved treatment regimens are not reimbursed.	Multi-cancer treated with chemotherapy	*Claims		Pathway adherence
*Aetna / Moffitt PCMH[69] *Aetna and University of Chicago PCMH[70]	*National health plan *Cancer center / oncology groups	Patient-Centered Medical Home	Aetna has partnered with several cancer centers and physician groups to implement patient-centered medical homes. There is limited publicly available information on the mechanics of these programs.				Pathway adherence / quality measure reporting
Alternative Payment Models: PCMH / ACOs							
Aetna / Texas Oncology US Oncology Pilot (managed by Innovent Oncology)[22,71]	*Large, national health plan *Physician practice management organization *Oncology benefit	Pathways Program	Physicians are paid a PMPM for qualified patients along with care management tools including pathways. Physicians received shared savings for drug utilization as well as hospital and	Multi-cancer	*Claims *EHR		Drug utilization, hospital visits, emergency department visits

	management company		emergency department visits.				
Florida Blue - Advanced Medical Specialties - Baptist Health South Florida Oncology ACO[44-46]	*Regional payer *Hospital *Oncology group	ACO	Providers are reimbursed under FFS. If quality metric performance measures are met, shared savings greater than 2% are distributed across partners.	Multi-cancer			Risk-adjusted financial threshold and quality measurement performance
FloridaBlue and Moffitt ACO[49]	*Regional payer *Cancer center	ACO	Providers are reimbursed under FFS. If quality metric performance measures are met, shared savings are distributed across partners.	Multi-cancer			Risk-adjusted financial threshold and quality measurement performance
Alternative Payment Models: Episodic Payments / Bundled Payments							
UnitedHealth Episode Payment Approach with 5 Large Medical Oncology Groups[13,37,38]	*National health plan *Large Medical Oncology Groups	Prospective Episodic Payment	Oncologists received ASP + an immediate episodic fee for chemotherapy administration reimbursement. The episodic fee was calculated using the drug margin (ASP-group's usual reimbursement) of the physician groups' choice of superior regimen for each episode + a small case management fee.	Breast, colon, and lung cancer treated with chemotherapy	*Claims	Yes	*Primary: Total medical cost per episode (risk-adjusted) *Secondary: Chemotherapy drug costs (risk-adjusted)

United Health Group Bundled Payments Pilot[39,41]	*National health plan *Large Cancer Centers	Prospective Bundled Payment	UnitedHealth Group has partnered with multiple cancer centers and oncology group to implement bundled payments.	Moffitt: Lung cancer MDAnderson: Head and neck cancer			Total cost of care for an episode
Medicare Oncology Care Model: Bundled Payment[33]	*Medicare *Commercial payer *Oncology groups	Retrospective Episodic Payment	Practices continue to receive FFS payment. In addition, they received a monthly enhanced oncology service (MEOS) of $160 for model implementation and infrastructure development. Additionally, performance-based payments based risk-adjusted threshold are available every six months. Participants may implement one-sided or two-sided risk models, with the two-sided risk models offering higher potential bonus payments.	Multi-cancer treated with chemotherapy	*Claims	Yes	Risk-adjusted financial threshold and quality measurement performance
Anthem Blue Cross of California - Valley Radiotherapy Associates Medical Group Breast Cancer	*State health plan *Large oncology group	Prospective Bundle/ Episodic Payment	Practices receive an episode-of-care payment (case rate agreement) for patients with stages 1-3 breast cancer because it usually requires outpatient radiation treatment only.	Breast cancer			Total cost of care for an episode

Episodic Payment[42]							
Highmark Cancer Collaborative Bundled Payment (in partnership with Allegheny Health Network and Johns Hopkins Kimmel Cancer Center)[43]	*Large regional payer *Oncology groups	Prospective Bundled Payment	Providers receive a bundled payment that is based on their past payments.	Multi-cancer treated with medication and radiation treatment for breast cancer			Total cost of care for an episode
Physician Developed Value-Based Oncology Reimbursement Models							
ASCO / Innovative Oncology Business Solutions (IOBS) COME HOME[17]	Broad-based ASCO program	PCMH	This is an oncology-focused patient-centered medical home that helps physician implement quality reporting requirements the QPP. Key initiatives included improving care coordination between physicians' offices and hospitals, expanding office hours, implementing methodological data collection, and developing and implementing clinical and triage pathways.	All cancer			

ASCO Patient-Centered Oncology Payment Model[72]	Broad-based ASCO program	APM	ASCO designed PCOP to help oncology practices implement an alternative payment model that fulfills QPP. The program centers on implementing value-based care that are promoted through additional enhanced practice service payments. Performance and risk are measured through pathway compliance and quality measure reporting. More advanced options include 1) a consolidated payment for oncology practice services and 2) virtual budgets for oncology care. ASCO has submitted PCOP to the Physician-Focused Payment Model Technical Advisory Committee for review and guidance on how to implement one-sided and two-sided risk.	All cancer			Quality measure performance and pathway adherence
LUGPA Prostate Care Episodic Payment[73]	Broad-based LUGPA program	APM	Large Urology Group Practice Association (LUGPA) has designed an alternative payment model episodic to fulfill QPP requirements. Specifically, episodic payment for patients with newly	Prostate cancer			Quality measure and utilization performance

			diagnosed prostate cancer, with localized disease. Performance-based payment would be based on meeting quality measure performance and enhanced utilization.				
Risk-Sharing Agreements							
Novartis-CMS VBP arrangement for Kymriah[59]	*Government health plan *Manufacturer	OBC	While priced at $475,000 per treatment, CMS will only reimburse Novartis if certain pediatric and young adult patients with a form of acute lymphoblastic leukemia respond within the first month of treatment.[59]				Response
Genentech-Priority Health Avastin VBP arrangement for Avastin[56]	*Health plan *Manufacturer	OBC	This OBC tied PFS survival to payment of bevacizumab in first-line, stage IV, non-small cell lung cancer patient. Specifically, the rebate was indirectly proportional to the length PFS under six months. Claims, imaging, and EHR data was used to assess whether the reasons discontinuation under 6 months was due to progression or toxicity, which were eligible for the	Non-small cell lung cancer	*Claims *EHR		PFS

			rebates, versus provider or patient preference.				
Genomic Health / UnitedHealth Group Oncotype DX, Assay for Breast Cancer (US)[74,75]	*Health plan *Manufacturer	OBC	If the number of women who used Genomic Health's oncotype diagnosis tool, which aimed to optimize chemotherapy and receive chemotherapy were greater than the pre-determined threshold of chemotherapy use, a lower price would be triggered with UnitedHealth Group.	Breast cancer	*Claims		Number of patients threshold
Express Scripts AstraZeneca VBP arrangement for Iressa[58]	*Manufacturer *PBM	OBC	For Iressa, Astra-Zeneca would reimburse the full costs of Iressa to Express Scripts (ES) if the patient discontinued prior to the third fill.	Lung cancer	*Claims		Duration of therapy (proxy for PFS)

CVS Transform Oncology Value Program[57]	*Manufacturer *PBM	OBC	For breast cancer, CVS has implemented a cost cap program, where if the plan's average cost is above a pre-determined threshold, the manufacturer must provide an unspecified value. For non-small lung cancer, the manufacturer must provide unspecified value if the patient progresses to secondary therapy with lab data confirmation.	Breast cancer and non-small cell lung cancer	*Claims *EHR		Breast Cancer: Pre-determined average cost threshold Non-small cell lung cancer: Secondary therapy use (proxy for disease progression)
Indication-Based Pricing							
Express Scripts Oncology Care Value Program in partnership with Accredo Specialty Pharmacy[54]	*PBM	IBP	Express Scripts's indication based pricing program aligns cost with product outcomes.	Prostate cancer, lung cancer, and renal cell carcinoma			

* Please note that the lack of a specified data source or clinical registry does not suggest an absence, but rather no publicly available information on it.

** Cardinal Health, NantHealth, New Century Health, US Oncology's Innovent, and Via Oncology are examples of third party oncology benefit managers that have developed and maintain evidence-based oncology pathways. They partner with payers and provider groups and help with pathway

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