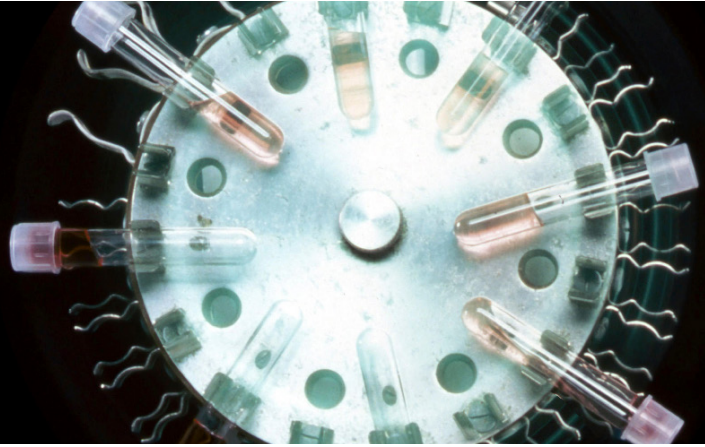


The evolution of oncology payment models: What can we learn from early experiments?



Executive summary

Pioneering health plans and provider groups are experimenting with value-based payment models in oncology to try to improve the cost-effectiveness of cancer care. They are piloting these models in the commercial market—financial incentives for adhering to clinical pathways, patient-centered medical homes (PCMHs), bundled payments, and accountable care organizations (ACOs)—and it is uncertain which will achieve the dual goals of improving outcomes and controlling costs. We interviewed health plans and providers participating in emerging payment models to review early results (financial and clinical), understand which approaches are working, and discuss considerations for these models' future evolution. Key findings from our qualitative research and analysis of oncology claims are:

- PCMHs and bundled payments without downside risk are the most common types of payment models being implemented among those we interviewed.
- Regardless of payment model, early health plan and provider collaborations have identified successful strategies to reduce unexplained variations in care and control costs. Common elements of these strategies include:
 - Technology and analytics to help practices and plans better understand existing patient populations and drivers of variability
 - Clinical pathways to help direct physicians to the most cost-effective treatment approaches
 - Patient-centric approaches such as 24/7 patient access, use of mid-level clinicians to direct patients to the most appropriate care setting, and shared-decision making

- Several of the early pilots have lowered costs by reducing variability in drug spending and using fewer emergency room (ER) and inpatient admissions. (See Table 2.)
- Applying these results to our analysis of commercial plan claims data shows that implementing these strategies can reduce spending by 22 percent across 1,385 episodes studied. Episodes include all costs over a six-month period, starting at the first dose of chemotherapy. This savings estimate could be considered conservative; the analysis evaluated stage 1 breast cancer patients where the variability in using high-cost services tends to be lower than patients with more advanced disease.
- While successful in reducing costs, most pilots to date have described performance on key quality measures, such as survival, recurrence, and complications, as staying the same; a few have seen improvement.

It is unclear how value-based payment models might impact the uptake of newly available, expensive treatments. Implementing evidence-based pathways could, in some instances, increase the use of new treatments and diagnostics, potentially resulting in cost offsets in other areas. Current pilots are experimenting with different approaches to allow for the use of these treatments, such as carve-outs, stop-loss provisions, and adjusting bundle prices on a contemporaneous basis.

New payment models in oncology are likely to continue to emerge and expand, partially driven by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which establishes financial incentives for participation in the Centers for Medicare & Medicaid Services' (CMS) newly established Oncology Care Model (OCM). Financial risk-sharing should increase over time and, in the near term, payment models are likely to focus on the use of clinical pathways and patient-centered approaches as part of PCMHs. Barriers continue to exist around tailoring payment models to cancer sub-types, capturing data to evaluate models, and bringing models to scale.

Life sciences companies should expect to face increasing hurdles to market adoption as physician-administered drugs are included in payment models and clinical pathways increasingly drive prescribing behavior. All stakeholders, including health plans, providers, government, employers, and life sciences companies, should work together towards improving the cost-effectiveness of cancer care.

Background

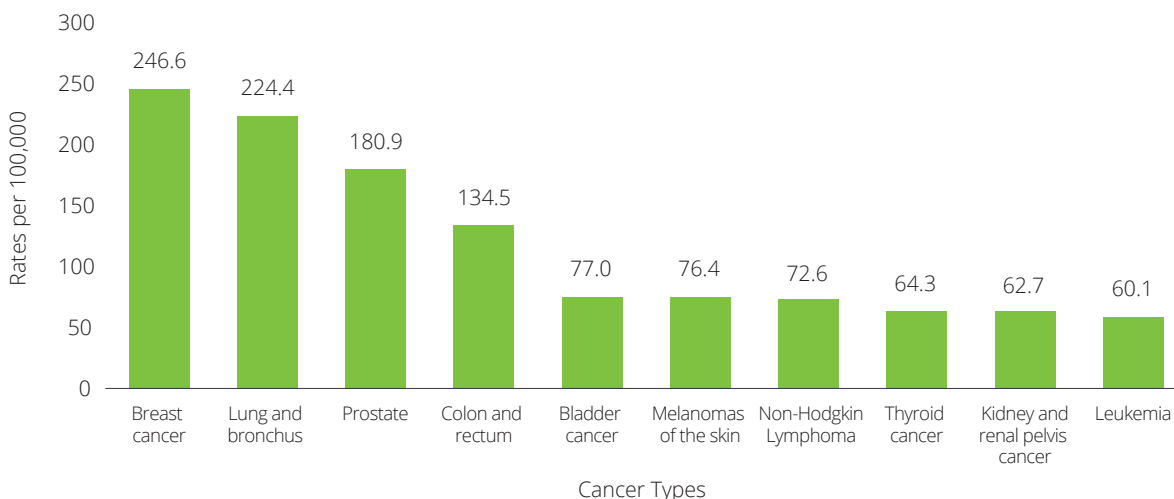
The cancer burden is substantial

About 14.1 million people are living with a cancer diagnosis, and an estimated 1.7 million new cases will be diagnosed in 2016.¹ An estimated 39 percent of Americans will be diagnosed with cancer at some point in their lives.² On a global level, the incidence of cancer is expected to increase by 70 percent over the next 20 years.³

According to the Centers for Disease Control and Prevention (CDC), from 2009 to 2013 breast, prostate, and lung cancer had the highest incidence rates (Figure 1). In 2014, mortality rates were highest for the following cancers: lung (27 percent), breast (nine percent), colorectal (seven percent), and prostate (five percent).⁴

Cancer is the second-leading cause of death, and it is estimated that 595,695 people will die from cancer in 2016. However, mortality rates have been declining over the past 20 years as a result of earlier detection and treatment advances. Survival rates have also been increasing; 67 percent of patients are expected to survive five years or more.⁵ Earlier detection and increasing survivorship adds complexity to cancer care.

Figure 1. Incidence rate across top 10 cancer types



Source: National Cancer Institute, Surveillance, Epidemiology, and End Results Program, "SEER Stat Fact Sheets," <http://seer.cancer.gov/statfacts/>.

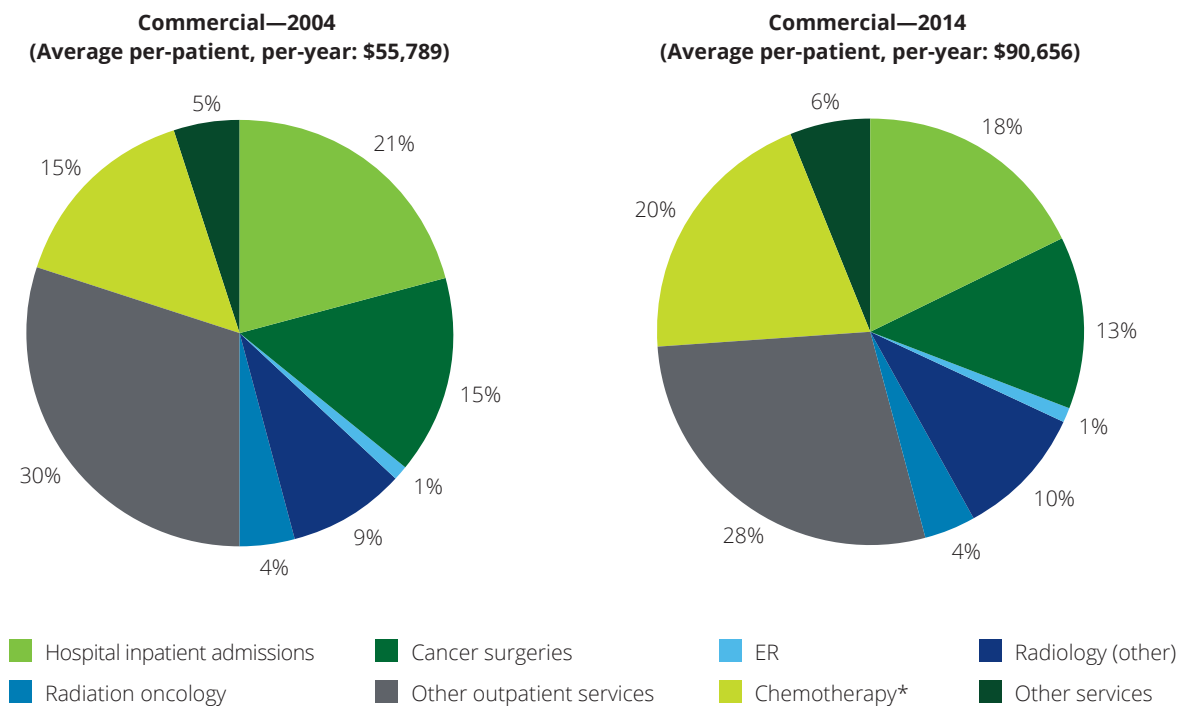
Key drivers of oncology spending

The cost of treating the United States' large and growing population of cancer patients is about five percent of US health care spending—and increasing.⁶ Direct cancer costs were estimated to be \$124.6 billion in 2010, and are projected to grow to \$158 billion—\$173 billion by 2020, reflecting an increase of 27 to 39 percent.⁷

The increase in spending on cancer care is driven by population factors and advances in therapeutics. Population factors include aging and increasing insurance coverage. Also, cancer is diagnosed earlier and patients survive longer. Advanced surgeries, radiation therapies, and anticancer medications—including advanced immunotherapies and targeted therapeutics—are increasing treatment costs.

The majority of cancer-care-services costs are for outpatient services, followed by inpatient admissions and drug spending. A Milliman analysis on changes to the percentage contribution of these services over time shows that the per-patient cost of drugs is increasing at a much higher rate than other cost components, driven largely by specialty drugs; spending growth has slowed in other components (Figure 2). The Milliman analysis also shows that the portion of per-patient per-year spending for drugs (biologic chemotherapy, cytotoxic chemotherapy, and other chemotherapy and cancer drugs) has increased from 15 percent to 20 percent, while the commercial cost contribution from hospital inpatient admissions has decreased, from 21 percent to 18 percent.⁸

Figure 2. Contribution of services to overall spending for cancer care



*Includes cytotoxic chemotherapy, other chemo and cancer drugs, and biologic chemotherapy.

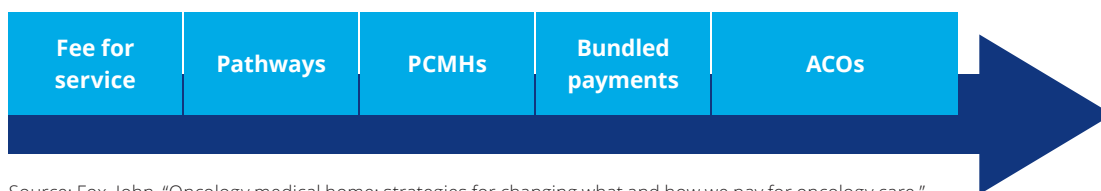
Source: Fitch K, Pelizzari PM, Pyenson, B. "Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014." April 2016, <http://www.communityoncology.org/pdfs/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf>.

Value-based payment models in oncology

As a result of oncology spending growth, health plans and providers are experimenting with innovative payment models with the dual goals of containing costs and improving patient experience and clinical outcomes.⁹ These oncology payment models include financial incentives for adhering to clinical pathways,

PCMHs, bundled payments, and ACOs. The models build upon each other to increase physician accountability and the level of financial risk (Figure 3). Some health plan and provider organizations are piloting multiple different model types or hybrids.¹⁰ Details and examples are discussed in Table 1.

Figure 3. Level of physician accountability and financial risk across oncology payment model types¹¹



Source: Fox, John, "Oncology medical home: strategies for changing what and how we pay for oncology care," presented at Michigan Cancer Consortium, Michigan, June 19, 2013.

Table 1. Value-based payment models being piloted

Model	Mechanics of the model	Examples
Financial incentives for adhering to clinical pathways	<ul style="list-style-type: none"> Clinical pathways are evidence-based protocols that direct prescribers to the leading, and often most cost-effective, treatment regimens. Oncologists are paid a care management fee for adhering to the pathways. The health plan defines a process by which adherence rates to the pathways and clinical outcomes can be measured and communicated back to provider practices. 	<p>WellPoint Cancer Care Quality Program</p> <ul style="list-style-type: none"> WellPoint Cancer Care Quality Program began on July 1, 2014, and includes cancer treatment pathways for breast, lung, and colorectal cancer. The program allows physicians to compare planned cancer treatment regimens against evidence-based clinical criteria. Identifies the cancer treatment pathways that have been shown to be effective, lower in toxicity, and cost-effective.¹² Oncologists are paid \$350 per month per patient for adhering to clinical pathways.¹³
PCMH	<ul style="list-style-type: none"> This model is focused on improving coordination and establishing partnerships among patients, physicians, and patients' families. Most plans pay practices a per-member-per-month fee (PMPM)—the fee goes towards practice investments for care transformation. Practices are expected to comply with evidence-based medicine, and are measured against quality metrics; claim-based utilization measures (i.e., hospitalization, ER utilization, and number of days in hospice); and total cost of care. 	<p>Aetna</p> <ul style="list-style-type: none"> Aetna and Moffitt Cancer Center formed a new model providing care through open scheduling and evolved communication between physicians and hospital staff.¹⁴ The model intends to focus on the patient's entire cycle of care (acute care, chronic care, preventive services, and end-of-life care). The model relies on Moffitt's clinical pathways system to identify treatment regimens.

Table 1. Value-based payment models being piloted (continued)

Model	Mechanics of the model	Examples
Bundled payments	<ul style="list-style-type: none"> • Bundled payments pay the health system or practice a fixed amount to cover a defined episode of care (covering a set of services) for a defined period.¹⁵ Attainment of certain quality measures also may be factored into reimbursement. • Narrow bundles cover the cost of one service (e.g., radiation) and broader bundles cover end-to-end services over the episode. • Duration of bundles can vary from a month to a year or more.¹⁶ • Payment types vary, with most services being paid a under fee-for-service (FFS) model, some being paid retrospectively or prospectively, and include an opportunity for performance-based bonus payments. 	<p>United Health Care (UHC)</p> <ul style="list-style-type: none"> • Three-year study conducted by UHC and five medical oncology groups around the country. • Covered 810 patients with breast, colon, and lung cancer.¹⁷ • An upfront fee was paid to oncologists based on the expected cost of a standard treatment regimen, and covered the standard treatment period, which is typically six to 12 months. In cases of cancer recurrence, the bundled payments were renewed.¹⁸
Specialty ACOs	<ul style="list-style-type: none"> • ACOs are at some financial risk for the total cost of care for their patients – not only costs per episode but for all services they receive. The focus is more on population health management than managing the costs inside specific episodes, but both may be targets. • Specialty ACOs often are led by oncology practices, which deliver a range of services.¹⁹ 	<p>Florida Blue/Baptist South Florida Health</p> <ul style="list-style-type: none"> • An agreement among Florida Blue, American Medical Specialties, and Baptist South Florida Health Oncology ACO with initial enrollment of 220 patients. • Cancers covered include the six most common types (cancers of reproductive systems, breast, colon, lymphomas, leukemias, and lung).²⁰
CMS OCM	<ul style="list-style-type: none"> • A two-part payment system, resembling PCMH and bundled payment models. • Practices will receive a \$160 per-beneficiary-per-month (PBPM) Monthly Enhanced Oncology Services (MEOS) payment to help manage and coordinate care. • Practices may receive a retrospective performance-based payment, based on savings and meeting quality measures. • Episodes start with the initiation of chemo and include costs for chemo and other services for six months.²¹ 	<ul style="list-style-type: none"> • OCM is a multi-payer model and high-volume cancer types (for which benchmarks can be calculated) are included. • The model was announced in July 2015 and in June 2016, 195 physician group practices and 16 health plans announced their participation in this coordinated cancer care initiative.²²

Value-based payment models in oncology: Which are most prevalent?

Some health plans, health systems, and oncology groups are experimenting with various payment models with the intention of reducing unexplained variations in care, controlling costs, and improving patient outcomes. While there may be opportunities to improve value through broader population health strategies including prevention, earlier detection, and better survivorship management, these pilots focus on opportunities associated with acute presentation of disease.

We interviewed 18 individuals from health plans, providers, and clinical pathway developers that are participating, supporting, or evaluating payment models to understand what they are doing, what approaches are working, and their considerations for the future evolution of these models. Among the interviewees, the most popular payment approaches are PCMHs or bundled payments. Below are details on the types of models the interviewees' organizations are piloting:

- **Clinical pathways:** One health plan offers a financial incentive based solely on adherence to clinical pathways. However, most interviewees said that clinical pathways are an important tool to reducing variability in care and cost, regardless of the payment model being implemented.
- **PCMH:** All providers participating in a PCMH received payment from a sponsoring health plan to invest in care coordination, but use of this funding varied. (See section, *How are payment models working?* on page 8.)

- **Bundled payments:** The structure of these models and reimbursement mechanisms differed across each pilot. (See Figure 4.)
- **Specialty ACO:** One provider organization has implemented an ACO model. The ACO is reimbursed as FFS with shared savings and no downside risk. With more experience, the ACO plans to transition to capitated and risk-based payments.

Few oncology payment models currently incorporate the potential for financial loss, or downside risk; they are more likely to have only an upside reward or shared savings. Some plans and providers stressed the importance of collaboration in early implementation of payment models; specifically, defining shared goals of identifying opportunities to improve patient care and reduce cost. To that end, some plans felt it was too early for practices to start to take on risk, but instead focused on helping provider groups analyze their own data, identify opportunities for savings, and implement strategies to transform care. They view the progression towards risk-sharing as an evolution, and anticipate that providers may become interested in taking on risk as they start to see the upside potential.

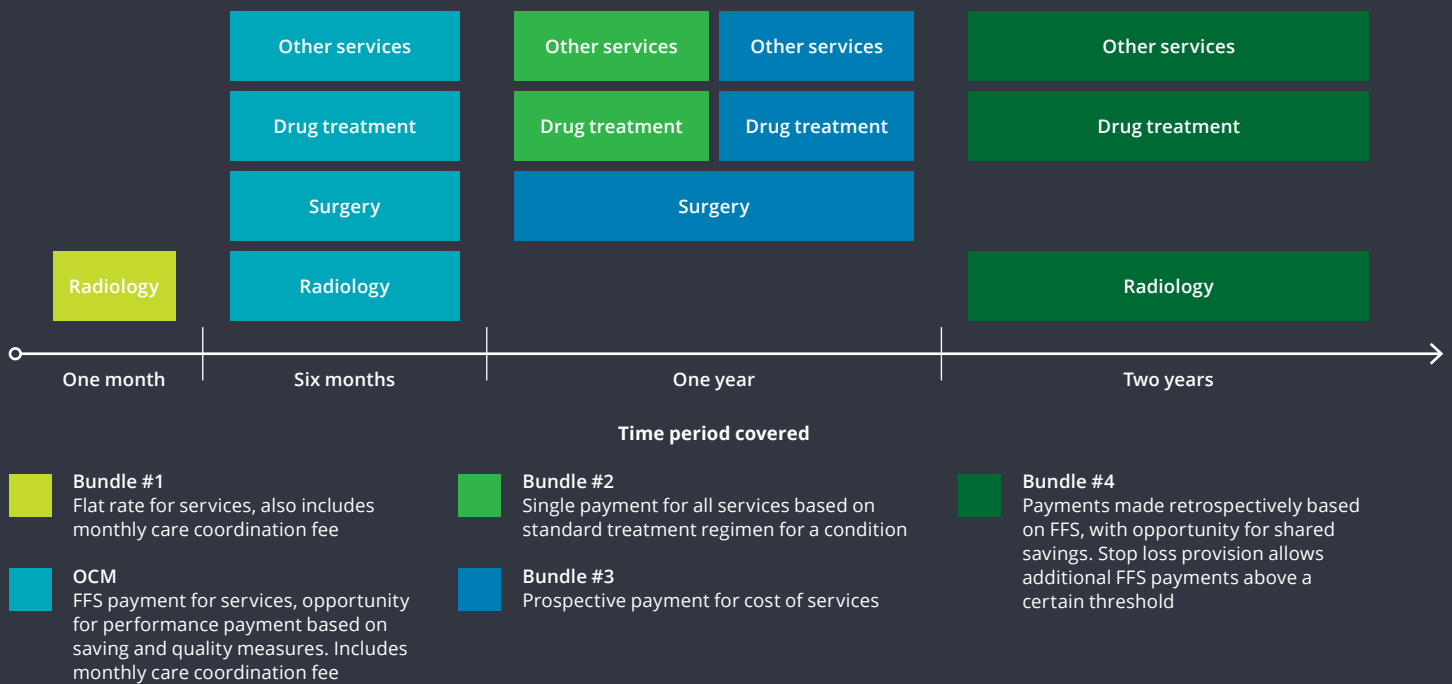
Most interviewees agreed that structuring a payment model in oncology requires delicately balancing standardization and flexibility. Models should take into consideration specific uncontrollable variables such as disease stage, severity, patient preferences, and introduction of new evidence or innovative treatments. These variables are likely what led to such variation in the payment models being piloted.

“Pathways are a first step to focus on accountability for how drugs are being used based on the best available evidence at the time that the patient is being treated. The medical home in our configuration is really focused on accountability; not only for how drugs are being used but for how patients are being managed. We are looking more comprehensively not at how do we treat cancer, but how do we treat the whole person and meet their needs.”—Health plan executive

What's in an oncology "bundle?"

Interviewees used different terminology to describe payment for a set of services, commonly referred to as a "bundled" payment, including case rates and episodes of care. Figure 4 describes four blinded versions of such bundles, alongside CMS's OCM, and the scope of what is included in each.

Figure 4. Examples of different bundle types implemented by organizations interviewed



Source: Deloitte Center for Health Solutions analysis.

While several organizations interviewed are piloting bundles, others strongly oppose the use of bundles in oncology care. These interviewees expressed concern over the underlying complexities of standardizing a bundle for a disease where there could be variation based on patient and disease characteristics, particularly when patient volumes for any particular bundle are low. Among the specific concerns raised are the:

- Collection of additional detailed information that is not typically included in claims data to appropriately define and measure bundle performance
- Need to formally integrate service lines (e.g., medical oncology, surgery, and ER) to be able to appropriately allocate costs or savings within a bundle
- Unpredictability of drug costs, especially given the recent pace of innovative new drugs becoming available. Providers fear that if they were to take on risk and a new expensive treatment was made available, the financial burden would fall onto the practice.

Beyond these operational considerations, some critics of bundled payments in oncology believe that these models will not help to reduce spending. Bundled payments may create short-term incentives to reduce cost, overlooking the potential long-term cost implications of choosing one type of treatment over another. In addition, bundled payments do not address other drivers of increasing spending in oncology care, including the issue of inaccurate or misdiagnoses. Patients may continue to receive inappropriate treatments despite provider participation in a bundled payment model.²³

How are payment models working? What capabilities and tools are needed?

Interview respondents point to several building blocks that can help providers transform their practices to reduce unjustified variability in oncology treatment. These building blocks include implementing technology and analytics, clinical pathways, and patient-centric approaches to improve care coordination.

Technology and analytics

“You have to know what you’ve done in the past to predict the future.”
—Provider leader

Interviewed providers stressed the need to invest in custom electronic health record (EHR) and data analytics technology to evaluate retrospective data and understand historical trends around treatment choices, outcomes, and costs. This level of analytics is required for defining and monitoring a bundled payment program. Further, analytics can help to identify high-risk patients and enable earlier intervention to reduce costs down the line.

Providers discussed some of the challenges around leveraging, integrating, and harnessing existing unstructured data to understand patient profiles and outcomes. Most traditional electronic medical record (EMR) systems don’t allow for the granularity needed to capture patient characteristics and outcomes in a structured way. Several oncology-specific technology platforms have been developed to help solve this challenge, which can enable more detailed data capture and analysis of patients with similar characteristics. (See sidebar: COTA.)

Interviewees also discussed the importance of sharing data, reports, and dashboards to drive transparency and physician accountability. One interviewee described an example where multiple practices came together to participate in a payment model pilot; one of the biggest benefits to the practices was the availability of information and data highlighting where they did well and where they had an opportunity to improve. He said that this data, “allowed them to get fairly open and frank about what they were doing that was different, how they were improving care, and they shared that with each other. It was a phenomenal experience, very collaborative, very patient-oriented; discussing what we can do to make patient care better was a constant.”

Recognizing the need for greater data sharing, the American Society of Clinical Oncologists (ASCO), committed to improving the quality of cancer care, announced its CancerLinQ initiative. CancerLinQ aims to improve patient care by analyzing data across physician practices that opt-in to the platform, and identifying patterns and trends. The data is also used to measure each practice’s care against that of its peers and recommended guidelines.²⁴

Real-time data sharing was the differentiator that made one provider’s partnership with one health plan more successful than with another. The provider attributed success to the fact that the health plan shared the data on a contemporary basis, rather than retrospectively, to allow for timely interventions.

Many providers and plans interviewed have partnered with external vendors for additional capabilities such as predictive analytics, clinical decision support, utilization management, prior authorization, and claims management. Some companies can also engage patients and help them make more informed decisions on treatment alternatives, benefit structure and design, and out-of-pocket costs of services.

COTA (Cancer Outcomes Tracking and Analysis) can stratify patients, identify optimal treatment plans, and quantify cost of care

A health plan and provider partnering in a bundled payment model are leveraging a technology known as COTA to triangulate among patient characteristics, utilization, cost, and outcomes. The COTA system captures much more precise data than standard EMRs or ICD-10 claims. Specifically, the COTA Nodal Address System (CNA) provides the ability to capture cancer subtypes and molecular characteristics, allowing for more “apples-to-apples” comparison of similar patients.²⁵ As the provider interviewee described, COTA “digitizes” patient characteristics into a profile, so physicians can look retrospectively to see how patients with similar profiles were treated and what the outcomes have been. This enables much more informed clinical decision making in real time. Further, the interviewee said that this level of data analysis can allow for definition of bundles that are more precise to cancer subtypes, looking retrospectively at outcomes and costs of patients with similar profiles.

“COTA is a data analytic platform that allows the application of precision medicine at the individual patient level while allowing total cost of care reduction at the population level. COTA extracts information from EMR, organizes it in such a way that you can look at it through a digital lens: outcomes and total cost of care, retrospectively and prospectively, so you can change clinical and utilization behaviors to optimize outcomes and reduce the total cost of care [by 20-40 percent] and it does it in real time.”—Provider leader

The health plan interviewee described using the COTA software to stratify its membership and define much more clinically precise bundles. COTA enables much easier administration of bundled payments since the technology can aggregate claims associated with the defined episode.

Biopharma companies have also invested in COTA’s platform with the aim of enabling precision medicine and more efficiency in cancer care. The companies can also benefit from COTA-generated real-world evidence (RWE) to accelerate the discovery of new medications to address unmet needs.^{26, 27}

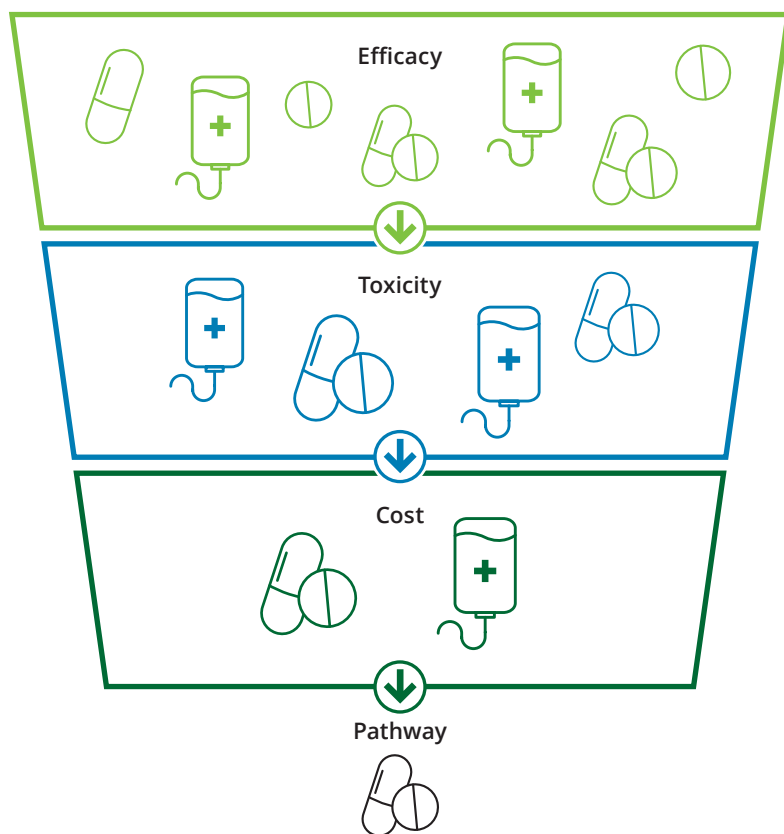
Clinical pathways and evidence-based protocols

Clinical pathways are clinical decision-making support tools that providers or health plans use to increase the number of patients being treated in accordance to evidence-based medicine. Roughly 50 percent of patients are currently being treated in accordance with evidence-based medicine; the adoption of clinical pathways may increase this percentage. Clinical pathways use algorithms based on evidence-based medicine to provide direction to oncologists on the course of treatment that would be most effective, least toxic, and least costly (Figure 5) for delivering cancer care based on a patient’s test results, diagnoses, and disease stage. In addition, clinical pathways can provide information that can direct physicians to alternative approaches if patients are not responding to the initial course of treatment.

The majority of providers and plans interviewed are implementing clinical pathways for clinical decision-making support, with the aim of reducing variability in treatment and drug spending independent of participation in a specific payment model. Variation in drug spending can be driven by several factors, including physician preference for drugs other than what is listed in clinical guidelines; off-label prescribing; and the use of clinical-stage drugs, especially in late-stage diseases where there are limited medical options available.

Plans and providers have varied approaches to defining, implementing, and enforcing pathways. Some health plans interviewed allow providers to design their own pathways, while others are much more prescriptive. Most providers interviewed have chosen to implement clinical pathways in their practices regardless of whether or not

Figure 5. Clinical pathway considerations



Source: Datamonitor Healthcare | Pharma Intelligence, 2016.

the pathway is required by a health plan or motivated by the provider's participation in a payment model. Some providers partner with an external clinical pathway developer to acquire a pathway tool; others have in-house committees or collaborate with other provider groups to define pathways tailored to a practice's preferences.

Pathways are built primarily based on National Comprehensive Cancer Network (NCCN) guidelines, defined nationally by oncologists, for close to 80-95 percent of cancer types. Three of the four clinical pathway developer companies interviewed also rely on other oncologists to provide input, either by reviewing clinical literature or by sharing patient experiences. Pathway updates can take as few as five days after a new drug or evidence is introduced, to as long as biannually. The most common evidence sources for updates are NCCN guidelines, scientific literature, and Food & Drug Administration (FDA) approvals.

All organizations interviewed incorporate cost as an element in clinical pathways. Some have started to incorporate information on "value" (note that there is no consensus definition of value, but calculations generally consider elements beyond efficacy, toxicity, and cost) from the NCCN evidence blocks and ASCO value assessment framework into clinical pathways. (See Appendix 1.) Most interviewees acknowledged that these frameworks are still early and cannot be used in isolation to define comparative benefits; instead, they consider measures of "value" to be useful information to engage patients in shared decision making.

For most of those interviewed, success in implementing pathways is defined as 70-85 percent compliance to the pathway. This percentage allows for some flexibility for acceptable variability in care that might result from patient characteristics, preferences, or the introduction of new treatments. When pathways are mandated, by either the health plan or provider, they can be used operationally to monitor and prevent any undesired variation in care. They can also be used to provide authorizations and reduce the administrative burden for on-pathways prescribing.

Providers can use pathways to gather RWE on cost, outcomes, and quality. They enter patient characteristics into the system to determine the right treatment pathway and this information, combined with treatment choice, cost, and outcomes, creates new evidence that can support further pathway tool refinement. One pathway developer is working to embed this evidence into pathway tools so providers can make treatment decisions in the context of historical outcomes experienced in their practices.

Providers can use clinical pathways to gather real-world evidence on cost, outcomes, and quality.

Physician-centric approach to enabling patient-centric care

“We transformed our practice. We have developed a well-defined care team with a very physician-centric approach that enables patient-centric care, which is about meeting patients’ needs, keeping them healthier, and keeping them away from sites of services that are unnecessary and expensive (e.g., ER, admissions).”
—Provider leader

Several provider organizations interviewed have invested in broader care transformation initiatives focused on patient-centricity. Some of the most effective strategies include expanded access, care coordination, and patient navigation or shared decision-making support.

Providing 24/7 access for patients, hiring mid-level clinicians to help direct patients to the appropriate care settings, or developing in-office urgent care services can expand access and improve care coordination. In fact, one of the requirements for CMS’s OCM model is 24/7 access—practices need to have someone who has access to medical records on call at all times. Practices offering this service expect that patients will be directed to the most appropriate care settings based upon their needs, which could prevent unnecessary trips to the ER. One practice relies on nurse practitioners to conduct this triage. Some practices have invested in oncology hospitalists who see patients if they do need to go to the ER. The hospitalists can quickly treat patients, avoid in-patient admissions, or reduce length of stay.

One practice has gone a step further and is investing in urgent care. Services needed to support chemotherapy patients, such as rehydration, could be more cost-effectively deployed in an urgent care setting.

Nurse practitioners or other mid-level clinicians could also proactively prevent ER visits by, for example, following up with a patient post-chemotherapy to see if they are able to keep food down. If not, they could ask the patient to come in for hydration before the symptoms get severe enough to require a visit to the ER or urgent care.

Interviewees described advanced care planning, or goals-of-care planning, as an opportunity to better align treatment plans with patient goals, focusing more on quality of life and potentially reducing unnecessary treatment at the end of life. Some patients, when given the choice, might choose palliative care over aggressive treatment. One health plan is partnering with a foundation to implement and offer training around advanced care tools for practices participating in an oncology medical home. As that health plan executive stated, “It wasn’t simply about paying for the service; that was easy to do. It was about building competency to provide that service.”

“It’s very clear from the data that we over-treat patients in a lot of areas of medicine, including cancer, but we don’t have discussions about patients’ goals and preferences to save money; we have it because of ethical principles, autonomy, and self-determination.”
—Health plan executive

What are the results of early value-based payment models?

Many new payment models have shown some early, but varied, success in reducing the cost of cancer care. Most of those interviewed attribute this success to a combination of elements: more efficient use of evidence-based pathways, increased access to lower-cost care settings, reduced need for managing patients in the

ER or in-patient facilities, and proactive care planning. Not all organizations interviewed were able to provide detailed financial analyses, but most anticipate that the same approaches will result in reduced costs at their organizations. Table 2 summarizes some of the early results from our literature analysis and interview findings.

Table 2. Drivers of financial savings and results to date²⁸

Model	Stated drivers of savings (ranges across pilots) ⁱ	Example savings realized
Financial incentives for adhering to clinical pathways	<ul style="list-style-type: none"> • Reduced drug spending (5-37 percent) • Reduced toxicity, resulting in: <ul style="list-style-type: none"> – Lower ER visits (6-40 percent) – Reduced admissions (7-36 percent) 	<ul style="list-style-type: none"> • Model 1: Reduction in drug costs of 37 percent over the course of a 12-month study • Model 2: 10 percent lower one-year cost per patient • Model 3: Estimated 3-4 percent reduction in total cost of care per year
PCMH	<ul style="list-style-type: none"> • Greater physician accountability and increased consistency in care • Reduced ER utilization (48-68 percent) • Reduced admissions (34-51 percent) • Reduced length of stay (21-44 percent) • Improvements in end-of-life care; increase in length of time in hospice care (34 percent) 	<ul style="list-style-type: none"> • Model 1: 35 percent annual reduction in total cost of care • Model 2: Estimated savings to the health plan of \$1 million per physician per year • Model 3: \$550 savings per patient in the first year
Bundles	<ul style="list-style-type: none"> • Reduced ER visits (30 percent) • Reduced admissionsⁱⁱ • Reduced in-patient days (17 percent) • Flattening out drug spending after historic increase of 15-18 percent per year 	<ul style="list-style-type: none"> • Model 1: Initial pilot savings of 34 percent in total costs. Spending for chemotherapy up almost 179 percent • Model 2: Reduction in PMPM costs; lower increases in oncology drug costs
Specialty ACOs	<ul style="list-style-type: none"> • Reduced drug spending due to pathways adherence (5 percent) • Reduced readmissionsⁱⁱ • Reduced length of stayⁱⁱ • Reduced radiation therapyⁱⁱ 	<ul style="list-style-type: none"> • Model 1: Overall savings of ~2 percent in the first year, with greater savings anticipated with expansion of the program to focus on additional services over subsequent years

i. Ranges reflect the high and low end of reported results across pilots within a payment model type.

ii. Quantified data unavailable.

Commercial claims analysis

Methodology

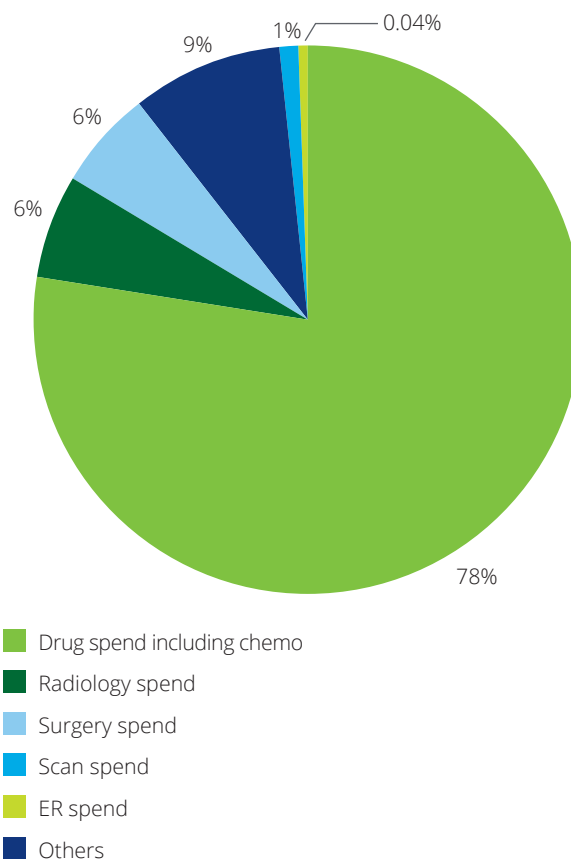
We analyzed 2013-2014 Truven MarketScan²⁹ commercial claims data for breast cancer patients to identify variability in spending (defined as the total amount of claims paid by commercial insurers) across major service areas, and estimate how the care transformation initiatives described above could impact overall spending. We categorized claims into episodes, including all services over a six month period, initiated by chemotherapy, mimicking the OCM episode definition. We focused on patients with stage 1 disease, since this early stage is least likely to be associated with significant clinical variation and associated variability in spending. Using this episode definition, we identified a total of 1,385 unique episodes. The episode contains claims related only to breast cancer and its treatment.

Key observations

For the 1,385 identified episodes of cancer, the average spending on an episode is \$30,000, ranging from \$500 to \$200,000. The majority of spending was for drugs, including all drugs prescribed and administered in the in-patient or outpatient setting (retail and over-the-counter drugs were excluded) (Figure 6). Since the episode covers a period focused on chemotherapy treatment, it is not surprising that the majority of costs came from drug spending.

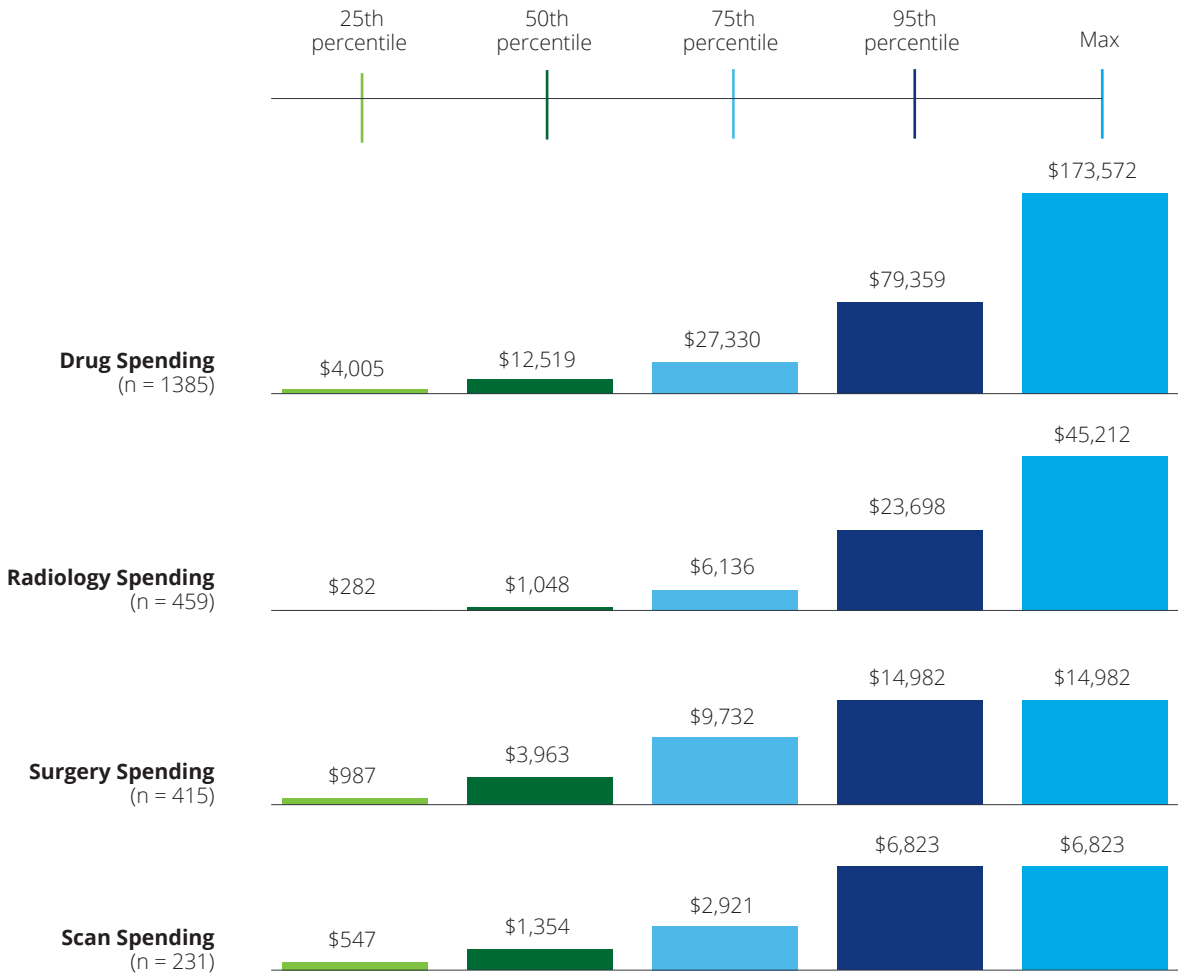
Most of the variability in cost across the total episode, as defined, comes from drug spending (Figure 7), followed by surgery and radiology. We ran a regression analysis to examine the contribution of each service category to variability, and our results were consistent. (See Appendix 2.) An analysis of high-cost drugs illustrates what treatments could be contributing to this spending. (See Appendix 3.)

Figure 6. Breakdown of spending in breast cancer episode; start of chemo plus six months



Source: Deloitte analysis of 2013-2014 Truven MarketScan commercial claims data for stage 1 breast cancer patients, episodes starting from first dose of chemotherapy plus six months.

Figure 7. Distribution of spending across key service categories with the breast cancer episode*



*Variation is shown for only the episodes that included spending on each service. The number of episodes that include radiology, surgery, and scan spending are indicated in parentheses.

Source: Deloitte analysis of 2013-2014 Truven MarketScan commercial claims data for stage 1 breast cancer patients, episodes starting from first dose of chemotherapy plus six months.

Savings opportunities

Our interview findings and secondary research point to two potential areas for savings:

- Drug spending could be reduced by implementing clinical pathways; and
- Patient-centered approaches could reduce ER visits.

The projected savings calculated are based on a hypothetical payment model that offers financial

incentives for adhering to a clinical pathway, resulting in a 30 percent reduction in drug spending; and a PCMH that results in a 60 percent reduction in ER utilization (assumptions derived from findings summarized in Table 2). Using these assumptions, we projected a total savings of 22 percent, or \$9.1 million across the episodes evaluated (Table 3). Note that the net savings would be impacted by PMPM fees offered as part of the payment models, which are not calculated here.

Table 3. Savings* from implementing value-based payment models

	Projected savings	Average	Savings calculation	Total cost savings for population
ER visits	60% reduction in visits	\$440 per visit and 1 ER visit per episode*	60% of the ER visits for 2.45% of episodes	\$9,141
Drug spending	30% reduction in spending	\$21,900 per episode	30% of mean spending for all 1,385 episodes	\$9,099,450
Subtotal				\$9,108,591

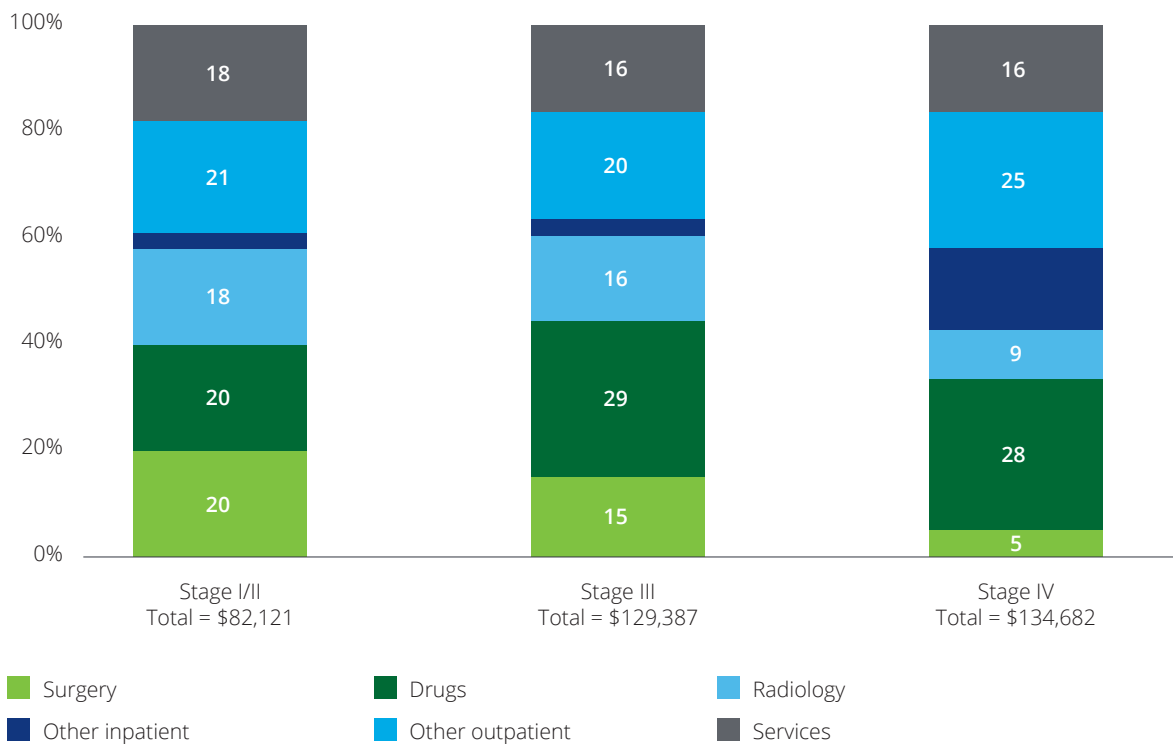
*Only the ER episodes were considered.

Source: Deloitte analysis of 2013-2014 Truven MarketScan commercial claims data for stage 1 breast cancer patients, episodes starting from first dose of chemotherapy plus six months.

This savings estimate could be considered conservative if evaluated in the context of spending trends across the broader breast cancer population. The analysis considers stage 1 breast cancer patients where the utilization of high-cost services tends to be lower than patients with more advanced disease. Based on a study conducted by the National Institutes of Health (NIH), stage 1 patients tend to spend less on drugs, in-patient,

and outpatient services than patients in later stages (Figure 8). At the same time, standardizing treatment and patient care for later-stage patients might be more challenging. Physicians may choose treatment options that may be not be considered a part of evidence-based pathways or enroll patients in clinical trials for patients with fewer treatment options.

Figure 8. Spending by breast cancer stage and services



Note: The total cost includes commercial claims paid for newly diagnosed cancer patients over a 24-month period.

Source: NIH, "Comparison of Treatment Costs for Breast Cancer, by Tumor Stage and Service," February, 2016.

What is the impact on patient care and outcomes?

Many value-based payment models have incorporated quality measures as a way to track the impact on patient outcomes. However, few of the early models seem to measure quality beyond utilization management measures (i.e., hospitalization, ER utilization, and number of days in hospice, inpatient bed days, infusion center use) and a few high-level outcomes measures (e.g., survival, recurrence, complications, timeliness of care, and patient satisfaction). Most interviewees described outcomes measures as not yet changing under new payment models. However, several interviewees did state that they believe increasing use of evidence-based pathways would reduce patient complications, hospitalizations, and improve overall survival. It is expected that greater compliance with evidence-based pathways, including NCCN practice guidelines, should improve overall disease-free survival since they are based on clinical trials that demonstrate improved survival against alternative approaches.

Several organizations described patient or referring physician satisfaction as key quality measures. One organization participating in a bundled payment model reported patient satisfaction at 90 percent for the duration of the pilot program. The same organization described satisfaction of referring physicians as growing from 50 percent to 80 percent, reflecting improved overall care coordination.

Incorporating meaningful quality measures will be increasingly important as value-based payment models start to include downside risk for providers, as the incorporated measures could influence treatment choices. As discussed in *Delivering Medical Innovation in a Value-based World*,³⁰ short-term or narrowly focused quality measures could make it difficult to recognize the value that new treatments may offer. Without a way to characterize this benefit, physicians may choose to avoid costly treatments in an attempt to meet financial metrics. To prevent this, stakeholders including quality measure developers, health plans, providers, life sciences companies, and academic researchers should carefully consider and continue to evolve the quality measures included in new payment models.

Do value-based payment models pose challenges for adoption of new therapies?

It is unclear how new payment models might impact the use of new therapies as they become available. The implementation of evidence-based pathways as part of alternative payment models could, in some instances, increase the use of new treatments. On the other hand, payment models that emphasize financial goals could deter physicians from prescribing more costly therapies.

Embedding molecular testing into care pathways and creating reimbursement transparency could lead to increased use of targeted therapeutics. One clinical pathway developer has built evidence-based pathways specific to the use of molecular testing. The pathways enable physicians to identify the right tests to order, labs to execute and interpret the tests, and determine which will be reimbursed. Transparency on what tests will be reimbursed could encourage the use of diagnostics and new treatments.

One health care provider described improved use of a targeted therapeutic from embedding RWE into clinical pathways. The pathways increased the use of genetic testing by 98 percent which, in turn, increased the prescribing of appropriate treatment and patient survival. Additionally, patients did not receive traditional chemotherapy and experience its negative side effects, reducing the need for ER, other costly services and, ultimately, the total cost of care. Diagnostics will continue to play an important role in determining the most cost-effective treatment pathway for patients (see sidebar: The role of diagnostics in managing cancer care).

The role of diagnostics in managing cancer care

Diagnostics will become increasingly valuable in cancer care as our understanding of tumor adaptation and drug targets continues to expand. The applications of diagnostics are rapidly expanding beyond simply determining appropriate use of individual targeted therapies. Genomic testing, immuno-sequencing, and other diagnostics can determine the profile of a patient's cancer and identify a set of treatment options that patients are most likely to respond to. New treatments, including immunotherapies, which harness the patient's immune system to identify and attack cancer cells, may become more tailored and targeted to address mutations in cancers resistant to other treatments. In the near-term, these advances in diagnostics and treatment may continue to increase spending in oncology. However, in the future, dynamic clinical-decision support tools that take into account multiple patient variables and also consider the financial trade-offs of treatment choices can help direct prescribers to treatments that can optimize patient outcomes and reduce cost over the long-term.

Organizations are experimenting with various approaches to make exceptions for the appropriate use of expensive new therapies as part of value-based payment models:

- **Make more frequent updates to clinical pathways** to reduce delays in adopting new therapies. Updates can take place anywhere from five days after new evidence is introduced to biannually. While clinical pathways do not usually directly dictate reimbursement, they do direct prescribers to preferred treatment options, which can often expedite authorizations. Adding cost-effective new therapies to clinical pathways could expedite the appropriate use of these treatments.
- **Precisely define bundles** based on cancer stage and biomarker status. Using software like COTA, which captures more granular information on patient characteristics, including genomic information, can help to define more accurate bundle prices that align with the most recent evidence-based medicine for a specific patient sub-population.
- **Adjust bundle prices frequently** by matching patients in a bundle with similar patients in the plan's FFS membership to calculate the benchmark price. If a new treatment is being reimbursed under FFS then the cost could be considered part of the updated bundle's total cost.

- **Carve-out new treatments** and reimburse them retrospectively as FFS. The carved-out payment for new therapies will be reviewed by a clinical team that determines if the costs associated with that product should be included in future bundle rates.
- **Incorporate a stop-loss provision** to reduce financial risk to the provider. An interviewed ACO is reimbursed on a FFS basis, and stop-loss provisions help to alleviate any financial risk associated with incorporating a new treatment into practice.

“The first responsibility of an oncologist is to make sure you have the best treatment available for your patients. I would not want to be constrained by any bundle that would force a financial decision to be made about adopting new technology. I think that it can be done, but any bundle that doesn't allow freedom to adopt new technology is certainly not the right thing for patients.”
—Provider leader

Future of value-based payment models in oncology

The implementation of MACRA should accelerate the evolution and adoption of value-based payment models in oncology care. MACRA offers incentive payments for providers participating in advanced alternative payment models (APMs), including CMS's OCM model. Under MACRA, clinicians participating in advanced APMs will receive a five percent increase to their payments from Medicare. This increase would be in addition to any potential shared savings or performance bonuses that APMs may qualify for.

On average, Medicare payments account for almost a third of physician practice revenue.³¹ OCM, when providers opt to take on two-sided risk, qualifies as an advanced APM under MACRA. In fact, 16 health plans and close to 195 providers have announced their participation in OCM. Organizations participating in OCM are starting with a one-sided risk arrangement, and will be allowed to take on two-sided risk starting January 1, 2017.

Financial risk-sharing is likely to increase over time. In the near term, value-based payment models will continue to focus on the use of clinical pathways and patient-centered approaches as part of PCMHs. As providers begin to invest in data, analytics, and patient-centered care, they may start to see reduced variability in cost and outcomes. These providers may feel more comfortable sharing risk, which may lead to greater adoption of more advanced payment models.

At the same time, barriers exist to the expansion of payment models in oncology. It is unclear that PMPM incentives will be sufficient for practices to cover required investments such as increased staff, training, and technology. As one interviewee pointed out, a lot of the funding for these investments is currently covered by the buy-and-bill system for physician-administered drugs. Value-based payment models in oncology aiming to change this payment structure will need to be effective enough in reducing the total cost of care to result in shared savings that can replace this revenue stream. It remains to be seen if this will be the case. In the meantime, smaller practices that lack the financing to make these investments may be more hesitant to experiment with value-based payment models.

Other structural and data-sharing barriers exist. Unpredictability of disease progression and care advances make it difficult to standardize treatments and associated payments. Data capture and reporting continues to be an administrative burden for many provider practices and health plans alike. Health plans may struggle to scale analytics and data-sharing capabilities across provider groups in the same way that those capabilities are currently tailored to individual pilots.

For many biopharma companies, the implementation of value-based payment models requires re-evaluation of development and marketing approaches. Drugs most likely to be impacted by new payment models are those that are administered in the physician setting, and used for more commonly diagnosed cancers such as breast, colon, and lung cancer. Implementing clinical pathways will likely increase price competition for products in drug classes with little clinical differentiation.

Clinical pathway developers, whether independent companies or provider groups, will become an increasingly important stakeholder to engage throughout the clinical trial design process and in the generation of RWE. Diagnostic companies should also engage with clinical pathway developers on applications of genomic testing, thinking more broadly than the historical match of one drug to one diagnostic.³² Presenting the value of drugs and diagnostics to these groups will require considering complex variables such as specific patient populations, indications, combination treatments, and pathway placement.

Lastly, the increasing emphasis on treating within the standard of care may reduce the appetite for use of high-priced innovative therapies in late-stage treatment. As a result, biopharma companies may need to shift development strategies towards demonstrating improvement over the standard of care in earlier lines of therapy, rather than entering the market as last line treatment.

Stakeholder considerations

Stakeholders across the health care system interested in improving the cost-effectiveness of cancer care should consider the following:

Health plans

- Initiate value-based payment models as a pilot with select provider groups. Establish the pilot as a collaboration aimed at identifying ways to improve outcomes and reduce costs for patient care.
- Focus on quality first, then establish a path towards shared savings and eventually move towards risk-sharing as providers become comfortable.
- Assist providers with timely data, analytics, and tools to support care planning and early interventions.
- Optimize oncology networks to include provider groups that are more closely adhering to evidence-based pathways.

Health care providers

- Identify a clinical practice leader to invest time and energy into care transformation. Physician leaders should be fully committed to quality, and given the autonomy to direct implementation of evidence-based protocols, monitor progress, and make required investments to improve care.
- Invest in technology to support analytics to understand causes of unjustified variability. Leverage analytics to understand real-world experiences on treatment approaches, costs, and outcomes to refine evidence-based protocols used in practice.
- Define and enforce clinical pathways that have demonstrated positive outcomes for patient populations treated.
- Focus on patient-centered approaches like expanding access and engaging in shared decision making. Consider hiring or using mid-level practitioners to support expanded access.

Biopharma companies

- Engage pathway developers in discussions regarding drugs in the pipeline and new indications being pursued. Pathway developers can provide useful input on development strategy based on their knowledge of customers' evidence requirements. Proactive engagement will enable pathway developers to better prepare for updates and help their customers anticipate budgetary impacts.
- Invest in generating RWE to support an expanding body of knowledge on what treatments work, for which populations, and in which settings, to help providers identify opportunities to reduce total cost of care.
- Connect drug price to value. Describe drugs' value in terms that extend beyond improved efficacy and toxicity. Absent of a consensus definition of "value," plans and providers interviewed are seeking information about how a drug would impact the total cost of care among their patient populations, for indications treated, and in combination therapy.
- Consider tying drug payments to outcomes such as survival, toxicity, and hospitalization, where these measures can be reliably and consistently measured. Consider leveraging new technology solutions to overcome the data collection challenges associated with administering outcomes-based contracts.

Diagnostic companies

- Consider applications beyond traditional companion diagnostics or matching a diagnostic to solely one drug.
- Engage pathway developers and biopharma companies around the evidence to support use of molecular diagnostics and companion diagnostics.
- Invest in RWE generation to demonstrate impacts to patient outcomes from the use of molecular diagnostics and companion diagnostics.

Appendix 1. Value assessment frameworks: What are they and how is value calculated?

As the US drug pricing debate continues, stakeholders are conducting analyses to define the “value” of drugs relative to each other or other treatments. Value-assessment tools often consider similar variables as those included in clinical pathways but also introduce additional elements such as affordability, novelty, and

relative cost-per-outcomes. Critics of these tools have pointed to some of the challenges in determining what the dimensions of value should be, how they should be weighted relative to each other, and the strength of evidence considered. Further, the calculations also often exclude patient characteristics and preferences.

Table 1. Oncology value assessment frameworks

Framework	Description	Key measures considered	Calculation
ASCO³³	<ul style="list-style-type: none"> The framework’s output is a net benefit health score, enabling patients to compare therapies 	<ul style="list-style-type: none"> Clinical benefit: based on overall survival, progression-free survival, and response rate Toxicity Palliation Cost per month/time off from all treatment 	<ul style="list-style-type: none"> Weight-based formula used for calculation of Net Health Benefit (NHB) = Score from Clinical Benefit + Score from Toxicity + Bonus Points
NCCN³⁴	<ul style="list-style-type: none"> Derivative from NCCN guidelines for different cancer types Helps facilitate value-centric discussions between providers and patients Individual parameters’ scores are used to build a visual block to illustrate the therapy’s value 	<ul style="list-style-type: none"> Regimen efficacy, safety Quality, consistency of evidence Affordability of regimen/agent 	<ul style="list-style-type: none"> Scores are given to each measure using a standardized scale Final scores of each measure are then used to build a 5x5 table
Memorial Sloan Kettering Drug Abacus³⁵	<ul style="list-style-type: none"> Enables measurement of the value of drugs using weighting defined at the user’s discretion 	<ul style="list-style-type: none"> Efficacy: improvement in overall survival rate Toxicity Novelty R&D: number of human subjects enrolled in approval trials Rarity Population health burden 	<ul style="list-style-type: none"> The price is calculated as the sum of the weighted average of the six key value drivers
ICER³⁶	<ul style="list-style-type: none"> Calculates a value-based price benchmark to link prices to patient benefits Uses multi-stakeholder inputs including patient advocates, clinical societies, pharma companies, and insurers The framework’s output is a value-based price benchmark that enables comparison across therapies 	<ul style="list-style-type: none"> Clinical effectiveness Incremental costs per outcomes Contextual considerations Comparative clinical effectiveness Incremental costs per outcomes achieved Contextual considerations Other benefits or disadvantages 	<ul style="list-style-type: none"> The key measures are used to determine a care value The outcomes of the measures are discussed and voted upon during public meetings as “high,” “medium,” or “low”

Appendix 2. Identifying the drivers of variability in spending across breast cancer episodes

We built a generalized linear model to identify the drivers of variability in spending across defined breast cancer episodes. A coefficient of variation of 1.08 indicates a high degree of variability in spending across the episode.

In building the model, the variables identified as significantly driving the cost (in decreasing order of significance) are:

- i. Drug spending
- ii. Number of scans
- iii. Surgery spending
- iv. Radiology spending

Considering the high variability in the total as well as other cost categories, the independent variables were split into three categories each, defined as low: zero spending; medium: spending below mean but greater than zero; and high: spending greater than mean. If spending increased from a low to high category, the contribution to total episode cost is largest for drug spending at 162 percent, followed by surgery at 57 percent, and radiology at 43 percent.

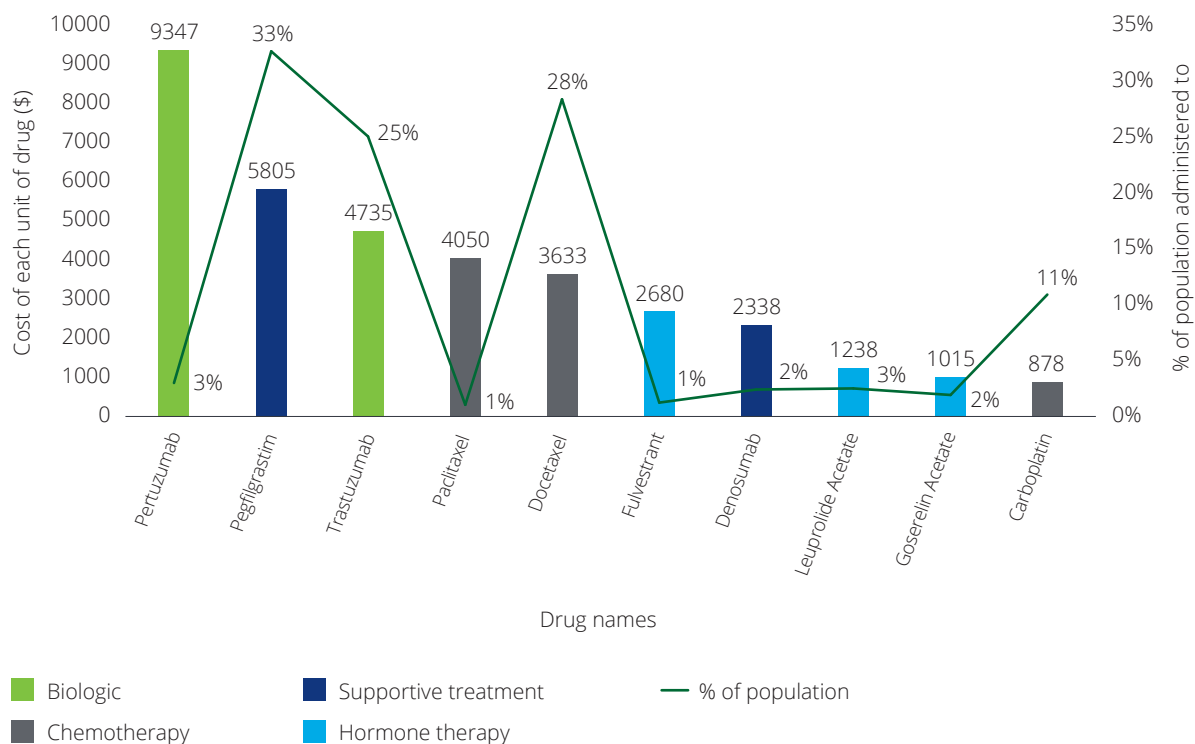
Appendix 3. Drug spending in breast cancer bundles

We analyzed the top 10 most expensive drugs (as determined by the unit cost calculated from claims data) prescribed to at least one percent of the population across the episodes evaluated. Two of the drugs prescribed are targeted therapies, three are traditional chemotherapy drugs, and three are hormonal treatments. Also among this group are two drugs used to control chemotherapy-induced side effects such as immunosuppression and bone health.

Use of some drugs in less than one percent of the population indicates that they might not have been used

in accordance with evidence-based clinical pathways. Clinical pathways are not applicable for 100 percent of the population, some patients might have a unique combination of characteristics that require treatment approaches outside of established pathways. It is not possible to determine if the treatments used were clinically appropriate, but if clinical pathways become more prevalent, the use of these drugs in this particular population might decline. Further, as providers take on financial risk for drug spending they may reconsider the use of some of these more expensive treatments, relative to the clinical value that they might provide.

Figure 9. Top 10 drugs by cost in stage 1 breast cancer episodes evaluated



Note: This analysis considers drugs which have been prescribed within at least one percent of episodes.

High-cost drugs that were prescribed to less than one percent of the population include:

- a. Rituximab (\$16,770 per unit) for three patients (biologic)
- b. Bevacizumab (\$14,400 per unit) for one patient (biologic)
- c. Tocilizumab (\$11,377 per unit) for one patient (biologic)
- d. Antineoplastic (\$5,243 per-unit average) for five patients (chemotherapy)

Source: Deloitte analysis of 2013-2014 Truven MarketScan commercial claims data for stage 1 breast cancer patients, episodes starting from first dose of chemotherapy plus six months.

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Acknowledgements

The authors would like to especially thank Becky Brian and Sophie Peltre for their contributions to defining this research project, and Priyanshi Durbha for her contributions to the commercial claims analysis included in this report.

We also wish to thank Tom Yang, Jodi Reynolds, Ralph Marcello, George van Antwerp, Amit Agarwal, Asif Dhar, Terry Hisey, Charles Firneno, Tony Olaes, David Betts, Mike van den Eynde, Felix Matthews, Candy Lurken, Aleem Khan, Mark Bethke, Yabo Wu, Kumar Kanisan, Nithya Baskaran, Atul Jain, Jim Whisler, Kristen DiObilda, John Keith, Andrew Ryscavage, Lauren Wallace, Wendy Price, Christina DeSimone, and the many others who contributed their ideas and insights to this project.

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