Optimal Oncology Alternative Payment Models

October 2018

VIEWPOINTS

Launching an advisory council to accelerate rapid learning across oncology alternative payment models

Executive summary

As Aviki et al. recently noted in a systematic review of alternative payment models (APMs) in oncology, despite the growing number of such models, "there is limited evidence to evaluate their efficacy."[1] Indeed, we do not yet understand these models' impact, whether they will ultimately prove to be sustainable, and whether they will effectively shift cancer care to a value-based paradigm. As such, some stakeholders believe there is a need for a continuous learning platform to rapidly identify failures and successes, as well as a need to collaboratively solve the ongoing challenges these models face.

To respond to these needs, a group of oncology care leaders has formed an advisory council to progress oncology APMs. Following a series of initial discussions in mid-2018, the council held its inaugural meeting on September 13 in Washington, DC, to focus on topics that the group collectively prioritized. Of these topics, data—which many see as the foundation for success in APMs—was a focal point of the meeting's agenda and factored prominently in the issues discussed:

- **Exploring the path to two-sided risk.** Participants assessed the level and types of risk that may or may not be appropriate for providers in APMs. They debated whether oncologists should be held financially accountable for costs outside of their control, such as drugs and medical costs that are not cancer related. Because some APMs are undoubtedly going to continue to include these elements, participants also explored the efficacy of tools to mitigate providers' risk, such as reinsurance/stop-loss products. Following a conversation with expert guests, some providers were dismayed to learn that the cost of a reinsurance/stop-loss product for an oncology population—which, by definition, is high cost and risky—was likely to be very high. Some, however, retained interest in exploring how these products could be effectively deployed in their models.
- **Supporting all sites of service.** Participants explored incentives outside of risk-based APMs that could make more providers accountable for delivering high-quality, value-based care. They focused on approaches to support community practices in making this transition. Some participants pointed to the benefits of closer, more collaborative support from payers; such support could include better provision of data, customized incentives and care-coordination fees, and referrals to third-party quality-assessment programs. Some remain concerned, however, that the benefits of these incentives do not justify the cost of providers' investment. Others recommended clinical pathways tools, although some cautioned that even these come at a price tag and require approximately 80% adherence to make a meaningful improvement in quality and cost containment.

- **Addressing the data conundrum.** Participants discussed how to better enable providers' access to high-quality clinical and cost data. Some emphasized that in APMs, providers need to focus on better using the data they already have, much of which lies in claims. Others focused on the increased burden that data input places on providers and brainstormed new business models for incentivizing data creation in electronic health record (EHR) platforms. They proposed potential partnerships where manufacturers could pay for data input, and in return, would be guaranteed an early look at the data generated.
- **Introducing emerging oncology APMs.** Some participants briefed the group on new oncology APMs they are developing, all of which will rely heavily on data. One model will focus on using genomics to make better-informed transitions to palliative care. Another localized model will engage self-insured employers and leverage sophisticated data analytics from payers. Finally, another will create more granular—and, presumably, accurate—payment categories through a state-of-the-art cognitive computing platform.

> *"I think that there is no model that will work everywhere. We need to have a variety of models that can fit a given population in a given community."*
>
> —Provider representative

- **Plotting the way forward.** Participants identified several topics they would like to see the council focus on in the future. Foremost among these was a continuing focus on data, including the need for oncologists participating in APMs to have a consistent set of meaningful EHR fields, and ways to reduce the time and resource burden on providers for data input, procurement, and utilization. Several participants called for continued examination of how best to structure risk in APMs and tools to manage it. Other proposed topics include taking a more multidisciplinary look at oncology, identifying good practices that APM models can employ to empower all sites of service, and assessing how emerging technologies like blockchain and telemedicine and trends like home-based care may impact APMs.

In closing, participants reiterated the need to learn more about existing models and for continued experimentation in oncology payment reform. The council will continue to serve its members by addressing these goals in 2019.

Introduction

> We need strategies and models that provide better care at a lower price, not just new models for the sake of new models and not new systems of payment for old systems that aren't open to real change.[2]
>
> —Alex Azar, Department of Health and Human Services (HHS) secretary

2017 was a watershed year for the oncology community as it saw the introduction of novel personalized immunotherapy treatments that made dramatic differences in the lives of patients with advanced cancers. These cutting-edge therapies, however, came with high price tags. Shortly thereafter, in 2018, leadership from the Centers for Medicare and Medicaid Services (CMS) reiterated its commitment to a value-based healthcare paradigm that holds providers accountable for costs.[3] The convergence of these two trends places even more pressure on oncologists today to generate more effective outcomes for patients at a lower cost.

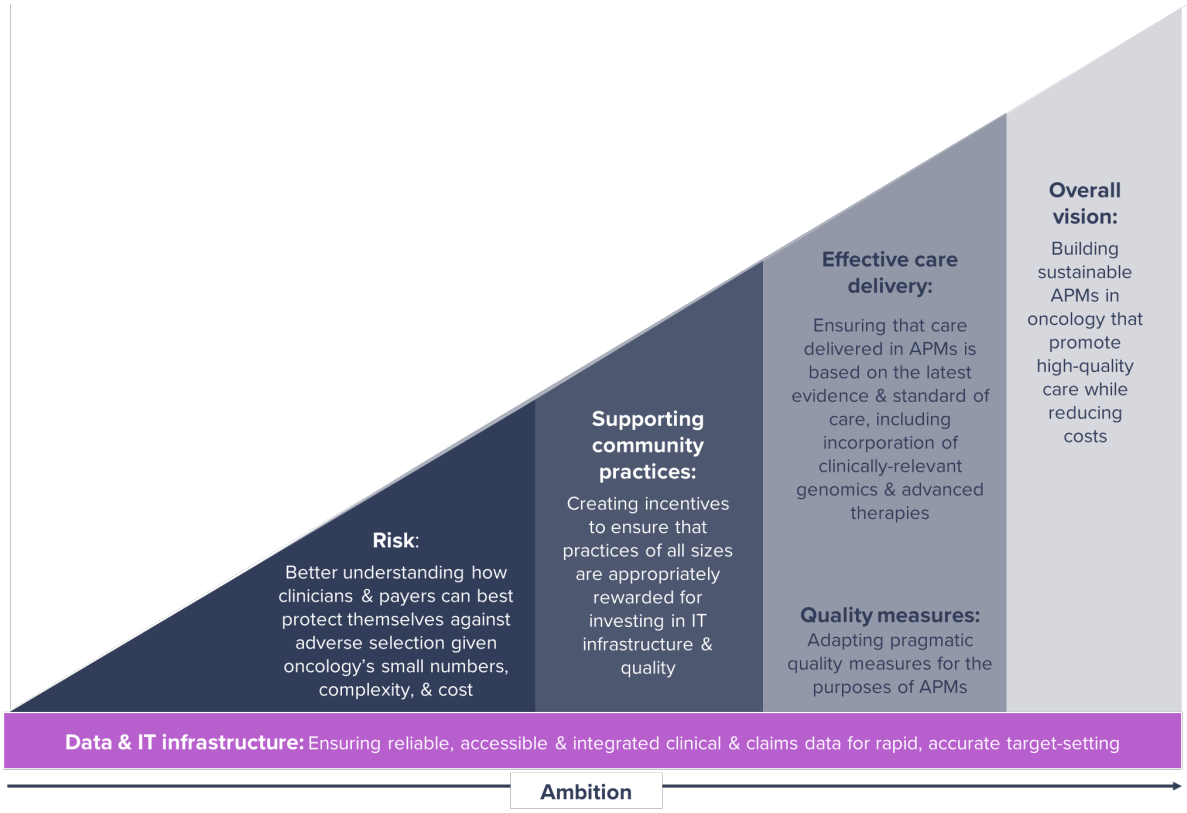
To help meet this challenge, many providers and payers are creating APMs designed to incentivize high-quality cancer care and reduce avoidable expenditures. But understanding precisely how APMs can meet both expectations and ensure the survival of a variety of oncology practices—ranging from small, independent community practices to leading centers of excellence—remains an open question. Therefore, payers and providers are carefully assessing the factors that contribute to the success or failure of APMs in this high-cost specialty. This includes the fate of the leading national model, the Center for Medicare and Medicaid Innovation's (CMMI) Oncology Care Model (OCM), as well as the many pilots that commercial payers and providers are implementing in diverse regions across the country.

An initial meeting of stakeholders engaged in oncology APMs convened in March 2018 to address the pain points that oncology APMs face in their implementation.[4] Following that meeting and a series of subsequent discussions, some participants elected to form an ongoing advisory council that could serve as an informal brain trust of payers, providers, and other stakeholders working to advance these new models of paying for cancer care in the United States. In forming the council, these stakeholders are eager for a continuous learning approach and a more dynamic, iterative testing environment for pilots.

The council's objectives are twofold: to serve as a cross-sharing platform to help leaders working in this space learn from one another more rapidly, and to incubate or accelerate potential solutions that could make APMs in this specialty more successful and sustainable. The council defines APMs broadly and will include any model outside of standard fee-for-service, including oncology-focused accountable care organizations, medical homes, and bundled or episode-based models. It includes models that are currently being piloted or are in development by public payers, commercial payers, and providers. The council is supported by Amgen and co-hosted by the American Cancer Society.

In discussions over the summer of 2018, council participants and additional relevant stakeholders discussed and ranked a broad list of topics they saw as critical to advancing APMs and shaping the

agenda of this group. These were, in order of priority: (1) addressing challenges to data integration and analysis, (2) streamlining quality measures, (3) ensuring effective care delivery under these new approaches, (4) developing incentives and support for community practices, and (5) clarifying the role of risk and reinsurance in APMs. The group considered a straw man to organize its priorities, as represented in the figure below.



Throughout the course of several pre-meeting discussions, it was clear most participants viewed data as the overarching stumbling block to the success of APMs in this specialty. Data challenges include the ineffective design and lack of standardization across EHR fields and the lack of interoperability across EHRs and claims data—all of which can lead to inaccurate risk adjustment and performance calculations. It also includes the need to reduce the burden on providers for data inputs and for procuring costly data sets and analytics tools that are typically needed for APM implementation. Members of the council expect to examine data issues consistently in future meetings. They will also explore the other four topics noted above to determine which of them they ultimately want to advance.

Following a series of agenda-shaping discussions over the summer, the advisory council held its inaugural face-to-face meeting in Washington, DC, on September 13, 2018. The meeting brought together a select group of APM innovators in oncology and guests who brought expertise to the risk, reinsurance, and data topics explored. Given the primacy members of the council gave to data-related challenges, this first meeting included a deep-dive session on data. Additionally, given the limited number of topics the

council could meaningfully address in a one-day meeting, quality measures were set aside for future discussion.

The following *ViewPoints* synthesizes the perspectives and outcomes from the September launch meeting while integrating broader-landscape analysis and views from the council's ongoing discussions and conversations with other key stakeholders involved in oncology APMs.

Exploring the path to two-sided risk: grappling with increased provider accountability

Recent administration statements indicate that the pressure for oncologists to undertake risk in APMs may be growing more acute in the near future. CMS head Seema Verma and HHS Secretary Alex Azar recently reiterated the department's commitment to transitioning providers more rapidly to two-sided risk models and to experimenting more with physician-focused APMs, including in cancer care.[5] "You're going to see more models from us," Verma told HHS's Physician-Focused Payment Model Technical Advisory Committee (PTAC) in September 2018, especially in high-cost areas like end-stage renal disease, cancer care, chronic disease, and other serious medical conditions.[6]

In this context, while the OCM and many oncology APMs are not yet mandating two-sided risk, some council members wonder if it may soon become a reality and thus are hoping to better understand how oncology practices can better manage risk. This is especially pertinent in an inherently risky, high-cost, and complex disease area like oncology. Specifically, many leaders in this space wonder whether tools deployed in other value-based payment models outside of oncology, such as risk adjustment and stop-loss insurance, can be successfully integrated into oncology APMs.

> *"I hope we can move away from practices taking on actuarial risk. We can't afford a model that could devastate the architecture of delivery of care."*
>
> —Provider representative

Defining appropriate levels and types of risk

Participants discussed several fundamental questions around the appropriate level and type of risk providers should be required to take in oncology APMs. Some asked whether provider accountability could be assured without building in shared risk at all. One subject matter expert said, *"In OCM, CMS is getting no guarantee they will save any money, so from the payer side, there's this question of how much savings is important? Do you get the value out of the model just by incentivizing the care transformation, or do you really need there to be a financial motivation—a guarantee of a certain rate [of savings]?"* Clinical pathways, care coordination fees, and other tools can support practices in shifting to value-based care without a transfer of risk from payers to providers, as discussed further below.

Regardless, working on the assumption that some degree of risk may be a feature of oncology APMs in the future, participants discussed the types of risk they deemed appropriate. Some rejected the idea of providers taking on actuarial risk or risk for factors outside of their control, such as medical costs not

related to oncology (e.g., trauma) or drug costs. One OCM participant said, *"If my patient who loves to ride a motorbike falls off a cliff, I'll be responsible for their care. That is something that I have no control over. Now, if it's neutropenic sepsis, I can control it very well, but I cannot predict who is going to ride a motorbike. Right now, I think 47% of the expenses from my practice were from elsewhere; I think that cost was assigned to our practice."* Furthermore, the unintended consequence of a model that builds in significant risk for factors outside of oncologists' control may result in a *"tournament model,"* as one participant described. In this scenario, smaller practices, which have a limited number of patients across which to spread their risk, may be forced to close or to consolidate to survive.

Some participants favored models for *"transactional risk,"* which only holds providers accountable for *"selecting the right drugs, the right treatment, and the right processes."* In such a model, providers would be given targets that are *"as accurate as you can make them,"* and rewarded based on hitting a target within a given range, since no provider would be able to *"come in exactly on the penny."*

Some models to date have embraced similar principles to mitigate the risks to providers. One participant gave the example of an experience with a commercial payer where the shared savings model the payer developed was risk-based but took trauma out of the equation. Additionally, the level of risk embedded into an APM's design can be structured so that minimal amounts of money are transferred to protect both providers and payers. This is the reality of many APMs today, some participants noted. A participant with experience in risk adjustment said that in an APM her organization piloted, *"we had a complex formula around caps and floors to mitigate the changes year over year so that nobody swung wildly,"* which helped manage the financial risk to providers associated with small volumes of members.

Assessing potential tools for risk management

Participants jointly assessed several tools that may protect providers participating in a two-sided APM. Sound financial targets, risk adjustment methodologies, and reinsurance are either already employed or could potentially be employed in oncology APMs; however, their implementation is not easy and comes with many caveats.

Creating accurate, clinically oriented targets

In many risk-based APMs, providers work to beat prescribed financial targets associated with an anticipated service or treatment. Participants therefore emphasized the critical importance of these targets' accuracy for providers, even more so than a decision to take on risk more broadly in an APM. This is because even if a provider did everything else right—including following quality measures perfectly—an incorrect target would still penalize them financially. *"If you're working against a target that was set incorrectly, you are going to lose money. And so you lose some of the motivation to be part of an alternative payment model that involves risk,"* a subject matter expert commented.

Additionally, in prospective models where you *"use factors that are knowable about a patient to predict costs,"* greater accuracy requires more granular detail on clinical factors that could affect a patient's course of treatment. Cancer's dynamism is especially challenging in this regard: a patient's response or progression can change over time, as many participants noted.

Considering these factors, adding more clinical detail to current payment models in an attempt to create more accurate targets will result in added complexity. One payer underscored this challenge: *"OCM and its payment methodology are complex—you must really spend a lot of time to understand the methodology. But when I hear conversations like the one today, I think, 'Well, it needs to get more complex.'"*

> *"We do all this risk adjustment to come up with the right price, but we also want to be able to measure the success of the program. The more complicated the risk adjustment model is, the less you see a correlation between quality improvement and the savings opportunity."*
>
> —Subject matter expert

Others emphasized that while there is a lot of variability, *"it's not random,"* and maintained that models that start with a robust clinical orientation are more viable. One participant shared some expertise in this regard: *"If you start with a model that is clinically driven for quality, performance, and excellence, and then you identify payment accordingly, and add on the variation and risk adjustments depending on severity of patient within that treatment, then the model becomes a lot more viable."* Indeed, models like the Making Accountable Sustainable Oncology Networks (MASON) model, which has been proposed to the PTAC, aim to leverage data-driven technology platforms to create highly precise, clinically based clusters of costs or oncology payment categories.[7]

Even clinically oriented models, however, have their challenges. Following accepted quality measures can result in unexpected costs if oncology providers are responsible for the total cost of care for a given patient. These additional costs can, in turn, cause providers to miss targets and fail to receive bonuses. One participant shared her experience with hepatitis screening and treatment as an example: *"A quality-of-care issue made us not achieve shared savings in one of our models. According to National Comprehensive Cancer Network guidelines, every newly diagnosed lymphoma patient should be screened for hepatitis B and C. If all drugs are in your shared-savings model, and if hepatitis is not being screened for in the community, then you may be out of alignment on overutilization of a very expensive drug [for hepatitis C treatment]. Risk is not just the rare motorcycle accident."*

Risk adjustment

Participants noted that models like the OCM employ risk adjustment to protect practices against full-blown actuarial risk. Risk adjustment aims to modify performance calculations so that providers are measured only on factors they can control.[8] APMs can adjust for specific patient characteristics, which may include sex, age, and social determinants of health; high costs of drugs, which can be accounted for through a novel-therapies adjustment; and exceptionally high-cost outlier patients, which can be omitted

from payment calculations through winsorization, a trimming process of the highest and lowest percentiles.[9]

Appropriate adjustment for the cost of drugs is particularly top of mind for key stakeholders in this space. Many providers protest that models like the OCM should not put providers at risk for the cost of drugs; however, as one participant underscored, *"The reality on the public-payer side is that drugs are not coming off the table, so how can we best design something that includes drugs?"* Indeed, CMMI, in its original design rationale, determined that removing drugs from the performance-based payment calculation "would have removed the incentive for high-value care in OCM … [and] would have created an incentive to use new drugs in cases where similar, equally efficacious drugs were already available."[10]

A recent Milliman analysis of CMS's novel-therapies adjustment explored its effectiveness and impact, and, using a hypothetical set of practices, confirmed its importance to practices that are frequent users of novel therapies. A participant reflected, *"The novel-therapy adjustment does what it was intended to do. It does protect people from the major downside of using novel therapies, but it only does that to the extent it was designed to. It doesn't protect you from 100% of the risk; it only protects you from some of the risk."* *For more details on this assessment, see the box below.*

The OCM's novel-therapy adjustment: an effective way to manage the risk of using new drugs?

The OCM's novel-therapies adjustment increases the financial targets that practices need to meet to ensure they are not penalized for using innovative, costly drugs. Eligible drugs are those approved by the FDA after 2014, and the adjustment only applies for on-label use.[11] Only practices that use a significant number of novel therapies more than non-OCM practices are eligible to receive the adjustment, as one participant emphasized: ***"It seems like a lot of people don't really understand that eligibility is measured in aggregate. You'll get folks who will say, 'I'm using a lot of this one drug. Shouldn't I be protected from that?' And the reality is that you have to be using a lot of all of the drugs on the list for that therapy adjustment to kick in."***

Consultants from Milliman recently teamed with staff members of the Pharmaceutical Research and Manufacturers of America to conduct a simulation of the experience of OCM practices with CMMI's novel-therapies adjustment methodology to gauge its impact. Using claims data from 2014–2015, the team applied the current adjustment methodology for OCM to a set of hypothetical practices for Part B drugs that were novel in that timeframe. From their simulation, the authors found that the adjustment "reduced the average loss per treatment episode by $758 (from $807 to $49) for large practices that use novel therapies often"—an amount that can make a meaningful impact on performance-based payments.[12]

The OCM's novel-therapy adjustment: an effective way to manage the risk of using new drugs? *contd.*

Their research raises several questions and opportunities for further research. A closer examination of the adjustment's impact on Part D drugs is one. The simulation also yielded some directional findings that the use of novel therapies for some cancers may reduce other types of costs in a given episode, a trend that the authors suggest warrants further investigation.

Finally, the article's findings indicate that, to the extent possible, a close examination of the impact of the adjustment on real OCM practices would be timely and beneficial. The authors emphasize that because OCM practices are likely to be innovators in value-based care and more sophisticated than the national average, they are also likely to be more frequent users of novel therapies: "The need for novel therapies adjustments or other mechanisms to account for increased spending related to novel therapy use may be greater in these practices than in other practices nationally."

Reinsurance/stop-loss

Seeing that in the future more models may require oncologists to take on risk, the group explored whether tools that are utilized to transfer and reduce risk in other areas of the healthcare system would offer potential solutions. Specifically, they considered reinsurance, which helps offset anticipated volatility for traditional liability-holding insurers, and stop-loss insurance, which self-insured employers use to protect themselves against large individual or aggregate claims. They considered whether these could be employed as a key design component in oncology APMs.

Currently, some conceptual models have given reinsurance/stop-loss some consideration, albeit at a high level. The American Society of Clinical Oncology's (ASCO) Patient-Centered Oncology Payment (PCOP) model, which is undergoing additional refinement, proposes an advanced option for a monthly virtual budget from which a practice could derive shared savings or absorb overages.[13] To protect practices from a high-risk case mix, risk adjustment and stratification would occur at the patient level. PCOP also proposes increased payment to practices for individual outliers and increased payment to practices with either individual or aggregate losses beyond a certain predefined financial threshold. As an alternative, practices could purchase reinsurance, the cost of which would be included in the payment bundle. The MASON model also includes a robust role for reinsurance in managing unexpectedly high costs that could jeopardize the business of participating practices.[14]

Reinsurance may also be relevant to the OCM. In the model's two-sided risk option, CMMI has employed a stop-loss set at 20% of episode prices.[15] As some providers underscored at the meeting, the potential benefits of transitioning from the upside-only track, which all OCM participants are currently in, to the two-sided risk option does not sufficiently outweigh the potential losses. Therefore, some meeting participants discussed whether a stop-loss or reinsurance product could not only help protect participating practices from this level of loss, but also incentivize them to make the transition to downside risk.

Despite the promise of reinsurance/stop-loss products in these concepts, subject matter experts cautioned that reinsurers would likely need to charge high premiums, given the size, volatility, and inherent high degree of risk associated with an oncology patient population. For example, for expensive individual excess claims that are driven by factors like hospital admissions—the types of claims that are likely to occur in oncology—*"reinsurers that are providing a product, if there's a product available, are trying to collect 25% margins. If you're looking for somebody to absorb that volatility, they want to collect a higher rate of return in order to do it,"* an expert noted.

> *"If reinsurers don't want to touch this risk, why would we? You'd be insane to do so."*
>
> —Provider representative

Participants acknowledged that given that level of premiums, the amount that practices would have to pay, presumably out of shared savings, could diminish the value of a reinsurance or stop-loss product. *"When you introduce reinsurance, you are now creating a negative—a subtraction to any shared savings developed or any other blended payment model developed. Providers have to factor that in as a front-end cost on participating,"* one said. Some participants, however, remain interested in further assessing the utility of reinsurance in their models.

Supporting all sites of service: scaling value-based cancer care

Many participants believe that payers should reward those who have invested in improving the technology infrastructure and quality of their practice without requiring them to initially participate in a risk-based APM. This is especially true for smaller, community practices for whom such investments are significant. They discussed other incentives for practices to shift to value-based care and debated to what extent these are scalable.

> *"Looking into encouraging providers to improve their care coordination and rewarding them with care coordination fees would definitely help. It may not help as much as addressing the drug piece, but it would help in reducing the hospitalization, ER visits, and operations stays. And I still believe that if we can reduce preventable hospitalization, like ER visits, we will have a savings potential between 7% and 15%, depending on what model you take."*
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> —Provider representative

Existing quality accreditation programs

There are several such paths that already exist for community practices. Some participants discussed their experience with quality assurance programs like those offered by the National Committee for Quality Assurance, which ultimately paved the way for their participation in the OCM. Commercial payers also offer similar initiatives, such as Blue Cross Blue Shield Association's Blue Distinction Centers for Cancer Care.[16]

However, others emphasized that such efforts need a stronger business case to be scaled to more providers

across the country, given that the investments in technology, additional staff, and other resources required for practice transformation are significant. One provider elaborated before the meeting, *"The issue is the potential value-add for practices—what's the business case? Payers need to define rewards and value. In other certification programs, malpractice insurers have offered a discount to practices, so that could be one incentive. We also need to help employers understand the benefits of distinguishing high-quality practices from others."*

Payer-led incentives

One solution that participants raised during the meeting is closer collaboration and alignment between payers and providers. Some reiterated that payers might be willing to work with providers on customized incentives. Payers can provide data, care coordination fees, and other tools to help practices make value-oriented care decisions, such as directing providers to third-party certification programs like the one offered by the National Committee for Quality Assurance. A provider noted, *"It was a care coordination fee that was our first step in buying into a practice transformation from fee for service to more like a patient-centered specialty practice."*

Payers are incentivized to help community providers with practice transformation to ensure the survival of lower-cost independent practices and prevent further consolidation in the marketplace. Indeed, several participants acknowledged that price differences across providers and diverse regions of the country create additional variables and diverse financial targets—which, in turn, make implementing national-level APMs like the OCM challenging.

Other tools: pathways and partnerships

Some noted additional approaches that can make the costs of transformation more manageable for practices. First, standardized treatment pathways can offer a step-wise approach for getting more providers comfortable with value-based care. A payer said, *"We had discussed a possibility that deploys clinical assistance support to our pathways program, starting with the community-based one- and two-person practices to establish their quality and so that they can deliver the right treatment to the right patient at the right time."*

A dedicated effort to scale the use of and compliance with standardized pathways to more providers in the United States could be a first step in improving quality and potentially bending the cost curve. A payer noted, *"When we looked at the numbers, 60% [treatment pathway compliance] is approximately the national average. If we can get up to 80% in oncology medical homes, we're pretty close to where we want to be."*

> *"Let's start with getting rid of waste, overutilization of medications. All the overutilization and waste of supportive agents that we see—it's mind-boggling. The cost curve will be bent if we start with decreasing medical waste—and that starts with accountability, it starts with standardization and pathway adherence. And we just don't have that now."*
>
> —Payer

Participants, however, emphasized that pathways—especially those marketed by providers and decision support tool vendors—come with a price tag and therefore still represent an investment to small practices. One participant proposed a solution for making them more accessible to more providers: *"I think pathways should be open source. Pathways are all based on the medical literature. It irritates me that certain companies want to charge for these pathways. I think it ought to be like a utility."*

As a second approach to making transformation costs more manageable, providers can engage in strategic partnerships to reduce their initial investments. One participant recounted an experience with this approach: *"We partnered with the local urgent-care center that's open 24/7. So after 5 p.m., when my patients have to be seen, they go to one center that's open 24 hours."* The partnership allowed the provider to save money by avoiding additional direct hires while ensuring that his practice offered a high level of quality.

Addressing the data conundrum: ensuring access to high-quality data to enable success in APMs

Many participants believe data is the key to success for oncology APMs and their greatest current obstacle. Providers underscore that in oncology, there is a dire need for high-quality, nimble, timely, and actionable data analytics tools to help them make decisions during their clinical workflow. Having access to such data, however, requires time-intensive inputs and costly investments by providers. Simultaneously, on the back end, vendors' manual curation processes, which are required to uphold data quality, can create time lags and increase costs. Therefore, participants brainstormed how multistakeholder partnerships and other collaborations could help expand access to high-quality data and APM decision-support tools.

> *"We would like to have data, and we would like to have data easily available to us. Right now, our practices are trying to hire data people to be able to do stuff. And we can't all afford external vendors. It's hard; it's expensive to do this."*
>
> —Provider representative

Bridging the clinical-claims gap

For providers, access to rich, dynamic, detailed sources of data is critical for determining accurate targets and making sound, real-time decisions on the value and costs of treatment. Currently, many APMs rely only on claims data to set financial targets and calculate provider payments. For many providers, this is not enough.

At the meeting, provider representatives stressed that it is critical to subdivide cancers into subtypes, biomarkers, comorbidities, measures of frailty, and so forth to be able to compare *"apples to apples,"* not only within a practice but also across a given region. This information is typically locked within EHRs and other diverse or unstructured sources (e.g., doctor's notes). Indeed, CMMI has acknowledged the limitations of using only claims-based data in the OCM and may integrate additional clinical data into its methodology in the future.[17] As a result of this divide, some contend that financial targets can fail to reflect the real cost variations that occur in specific types and subtypes of patients during their treatment.

That said, some subject matter experts emphasized the need for balance—or *"good enough data."* They underscored that claims data can yield useful *"low-hanging fruit"* about drivers of practice costs that can influence provider decision-making. Practices often underutilize claims data, they explained, as many physicians are distant from the information entered and how to analyze it. The data serves as a *"postmortem"* on treatment and examines the cost of the drug and other procedures. One participant underscored the value of Medicare claims data in assessing inpatient utilization: *"What's driving those readmissions? On claims, you have the diagnosis codes. In fact, you have multiple: Medicare is very strict compared to commercial payers; Medicare requires a minimum of seven diagnosis codes before they'll pay a claim, so the quality of data from Medicare is great. So you are able to look at not just the main reason for readmissions but also the diagnosis. You can ask, Is that something that really is avoidable? What can we do?"*

In brainstorming ways to bridge the clinical-claims divide, some participants expressed interest in understanding efforts that have used Surveillance, Epidemiology, and End Results Program (SEER) or cancer registry data to overlay clinical records with cost data. Indeed, the Hutchinson Institute for Cancer Outcomes Research (HICOR) did just this in a landmark analysis of cost and quality across cancer providers in the state of Washington. While HICOR did not do so for the purposes of awarding payment, participants were eager to understand how they were able to build and enable the use of their database. *For more information on HICOR's efforts, see box below.*

Integrating clinical and cost data: a case study from the state of Washington

In 2018, HICOR released a landmark report on the cost and quality of cancer care in the state of Washington. It is the first publicly available report to show "clinic-level quality measures linked to cost in oncology" and aimed to provide a more transparent look at the cost and quality of care across the state.[18] The selected quality measures were as follows:

- Recommended treatment for breast, colorectal, and lung cancer immediately following diagnosis, including estrogen and progesterone receptor testing (ER/PR) and human epidermal growth factor receptor 2 (HER2) status testing for breast cancer
- Emergency department and inpatient stays during chemotherapy
- Appropriate follow-up testing, including imaging and, for breast cancer, tumor marker testing
- Care relating to the last 30 days of life, including administration of chemotherapy within the last 14 days of life and multiple emergency department visits in the last 30 days of life[19]

Integrating clinical and cost data: a case study from the state of Washington *contd.*

The report captures and synthesizes data collected by HICOR from the Washington State Cancer Registry and the Western Washington Cancer Surveillance System. Registry data points included age, gender, census tract, date of diagnosis, tumor site, sequence number, stage, tumor size, histology, ER/PR/HER2/neu status, and date of death.[20] These data were combined with claims data from 269,000 matching enrollees from Premera Blue Cross, Regence Blue Shield, the Washington State Uniform Medical Plan, and Medicare.[21] To preserve the integrity of the collaboration for research purposes, all parties agreed to a two-year moratorium on using the data for contracting purposes.[22]

HICOR extracted up-to-date data from these sources on a quarterly basis and allowed practices to compare their achievement of quality measures to other practices in the region using HICOR IQ, an oncology informatics platform built from HICOR's database.[23] HICOR IQ aims to be a "single resource" for payers, providers, and researchers for information on quality, outcomes, and costs in cancer care.[24]

Whether HICOR's data integration and analysis efforts in Washington can be meaningfully scaled and used to make performance calculations is an open question. HICOR co-director Gary Lyman explained that the state of Washington was "fortunate" to be able "to link data from the insurers and Medicare with tumor registry data from the SEER program, which covers much of the state of Washington. We also have a separate Washington tumor registry that covers the rest of the state, so we are able to merge data from the insurance company data with the clinical data from the tumor registry, accounting for over 70% of the state residents."[25] Lyman also cited the level of commitment and cooperation across all parties as a key factor in enabling the sharing and transparency of data across stakeholders.

Finally, HICOR's use of cancer registry data also enabled seamless collection of staging data for risk adjustment. In aggregate, these aspects of the HICOR program may be challenging to replicate in different environments and in the context of APMs.[26] Some stakeholders with knowledge of the project noted that because data is ***"a business for payers,"*** especially national ones, payers may be reluctant to be involved in similar initiatives elsewhere.

Dealing with data entry and curation

Currently, the entire oncology data workflow is time and resource-intensive. This includes the time required for busy oncologists to accurately input data and the curation efforts required for vendors to validate the quality of the data. It also includes the cost for providers to procure, learn, and effectively use the necessary analytics tools to be able to participate in an APM. With these issues in mind, participants discussed several challenges that need to be addressed.

> *"There is a price tag to every tiny little bit of data."*
>
> —Provider representative

First, APMs and other quality initiatives require extensive box-checking and structured data entry from clinicians. During the meeting, many of the provider participants called for standardization across EHR fields relevant to APMs that would minimize their time and effort. A participant noted, *"If oncology groups determined that there are 30 indicators or fields that they want, that should be mandated to the industry. So if everybody building an EHR required these 30 things, those 30 fields should be there, in structured data, with information readily able to pull out. I think that's fair."*

Second, the data that providers receive from payers or vendors must be digestible. A payer noted, *"Provision of data from the payer to the provider is absolutely essential to an APM. But I think one of the more provocative questions is the expectation that the provider be able to somehow ingest that data and make something meaningful out of it."*

Finally, providers also want information that is dynamic and flexible. A provider lamented, *"EHRs are basically SQL databases. Why can't we just play with SQL databases and be able to sort and slice and dice the data? Why can't I have an EHR I can actually think with?"* In contrast, a subject matter expert cautioned that while *"there are aspects of EHRs that are very accessible as an SQL database, there's a lot of them that are very, very inaccessible as a SQL database."* Developing more sophisticated and easily queried data solutions is time intensive for vendors, and analyzing and curating unstructured data for meaningful elements requires significant resources. One expert noted, *"A lot of the rich information that we're talking about, particularly to characterize these populations, sits in documents, in things that get scanned in."*

Rethinking the data business model

Many of the above challenges, participants noted, could be solved with time and money. Therefore, they discussed the prospects of exploring new business models for data inputs, systems procurement, and analytics.

They wondered, for example, whether data entry by clinicians could be incentivized differently, potentially as a revenue stream to practices. The pharmaceutical industry could pay for data collection in exchange for some level of exclusive access to that data, given that industry is eager to obtain clinical and claims

data for research purposes. *For a case study from the field of genomics on a partnership that embraced similar principles, please see the appendix on page 21.*

In this spirit, other new multistakeholder partnerships offer promise in enabling practices of all sizes to leverage access to rich data and technology solutions to enhance cancer care. OneOncology, for example, is a new initiative—spearheaded by EHR vendor Flatiron along with founding practices Tennessee Oncology, New York Cancer & Blood Specialists, and West Cancer Center—that will unite over 225 oncology providers and empower them through Flatiron's data and technology platform.[27] Using the platform, providers will be able to access clinical and operational data and new research through a national network.[28]

> *"One of my big takeaways from this is an understanding of the data hole that we're encountering in oncology, which rests on the ability to create that data 'richness' which involves staging, metastases, acceleration, and genetics."*
>
> —Subject matter expert

Finally, some participants also proposed ways in which payers could better support practices with data, including bearing some costs. Commercial payers noted they could help providers with data provision, including regional data, if providers were aligned with the payers' mission to shift to value-oriented care. Others proposed a data *"opt-in"* function for commercial payers that would be similar to Medicare's Blue Button, which allows Medicare patients to voluntarily select to receive claims directly or to send them elsewhere. A similar function across commercial payers could enable the development of better large-scale data sets that providers could easily access and use.

Introducing emerging oncology APMs: sharing new concepts across a multistakeholder group

As noted above, this advisory council aims to serve as a cross-sharing platform for innovators in this space to more quickly learn about the elements of success and potential failures. In service to this goal, participants joined in an open exchange of ideas and updates on their models and concepts. Three of them shared highlights about new APMs they are developing.

Using genomics and data in end-of-life care choices

One payer shared a high-level concept to use genomics to inform decision-making on end-of-life care choices in a value-based, patient-centered context. This new model will use genomics and data to drive value and help providers make difficult decisions on when to initiate end-of-life care discussions with patients. It will closely engage payers, drug manufacturers, and genomics labs and focus on advanced cancers for which *"third, fourth, or fifth lines of therapy are not going to be helpful and can actually be more harmful,"* a payer with knowledge of the model described. The project will re-biopsy the patient and perform whole-genome-sequencing on the sample to determine if there are any mutations that warrant action, including use of therapy that may be off-label for a patient's tumor type but is a match for the

identified biomarkers. Developers would provide drug treatments at no cost in return for data on whether or not their treatment is efficacious in a different tumor type.

While, as some participants observed, the approach is similar to ASCO's Targeted Agent and Profiling Utilization Registry trial, involved participants noted, *"Our twist is that we are going to now make decisions on end-of-life care in those members that don't have actionable mutations and in those members whose mutations don't fit clinical trials."* [29] Some participants validated the model's use of large genomic panels. One said, *"We know which drugs are linked to actionable mutations today, but we don't know which drugs will be for actionable mutations in two years."*

Palliative care–related issues also arose in the data discussion, with some participants lamenting that quality measures for administration of chemotherapy in the final days of life, for example, or the number of days in hospice, fail to reflect the complexity of decisions that are often driven by patient preferences. In recognition of these complexities, this new model's approach to end-of-life choices will be rooted in genomic information, education for the patient, and shared decision-making with the clinicians involved.

Partnering with self-insured employers

Another participant described a pilot working with self-insured employers, a professional association, and an oncology clinic with multiple sites. In this model, which will be tailored to the local market, payers have agreed to ease prior-authorization and administrative processes and provide rich and expedient data if providers are adhering to National Comprehensive Cancer Network guidelines. *"We want to scrutinize the patient journey and understand what the costs are and the rationale for why people get admitted to the hospital,"* a participant involved with the project described. The employer involved has agreed to provide enhanced programs around cancer awareness, screening, adherence, and so forth. Providers will be paid through a care-coordination fee, similar to the OCM's Monthly Enhanced Oncology Services payment.

With regard to the pilot's long-term goals, the participant explained, *"Over time, we are going to look at the metrics in the pre- and post- period to see, Were you able to provide cost-efficient care? But also, the employer is more concerned with patient satisfaction, getting the right drug at the right time to the right patient, so ultimately that employer is most concerned with getting high-quality, cost-efficient care to their population."*

Refining a national alternative to OCM

Finally, some participants provided an update on the MASON model. They emphasized the model's intent to increase transparency by making all claims visible to providers before adjudication; to identify and categorize more granular clusters of costs; and to monitor triage and clinical pathway compliance to measure quality.

They also focused on the model's use of increased payments for administration costs—or *"facility fees"*—to compensate for the reduced margins participating practices will receive from drug procurement. This move will help remove the cross-subsidization from drug buy-and-bill margins that some providers use to sustain the financial health of their practices. Under the model, as one participant explained, *"reimbursement for drugs would be average sales price plus one."* It would also provide for a *"facility fee that reflects the real cost of infusion, to increase transparency in terms of being able to say, 'This is what it costs me to get the drugs out of the bottle and into the patient, so pay me that. Let me stop doing all this crazy cost shifting.'"*

> *"Oncologists live on the drug margin from our commercial payers, but we are dying under the drug margin—or the negative one—from Medicare. And right now, as Medicare gets bigger and bigger and commercial plans get smaller and smaller, that's one of the reasons oncology practices are selling to hospitals. We can't keep it up."*
>
> —Provider representative

The model will be evaluated by the PTAC later this year and, if approved by the PTAC and eventually by CMS, could serve as a complement to the OCM. ASCO also strongly supports the model, is engaged in ongoing collaboration with the MASON model's authors, and may consider merging it with ASCO's PCOP model in the future. One participant commented that MASON *"is the next step of what we need to do to make those targets more useful and to get the real-time data and make it more manageable."*

Plotting the way forward

The oncology APMs discussed during the meeting and reviewed in this *ViewPoints* remain, importantly, pilots. They are early-stage experiments to bolster the quality of cancer care in the United States while attempting to reduce costs. The formula for how to do so while preserving patient access and allowing providers of all sizes to thrive remains uncertain.

Participants of the advisory council affirmed their interest in continuing to address the many unanswered questions and challenges relating to payment reform in oncology. They reiterated that data continues to be first and foremost among these. Several echoed the need for standardization in EHRs of key clinical components and data fields that are relevant to implement and scale APMs. They proposed that the group work with key stakeholders to begin to encourage standardization and improvement. One participant said, *"I think it is very important right now for the oncology world to get the data sets and the fields that have to be in all the EHRs. I think until we have that figured out and everybody adopts it, we're going to have a real issue with data management."* Others also called for creative partnerships to help reduce clinicians' data entry burden and improve access to the high-quality data needed for decision-making in APMs.

Participants were also keen to continue to assess risk and risk-mitigation tools like reinsurance. One participant observed, *"I think that whole discussion [on risk and reinsurance] could have gone on for several hours."* Moving forward, some wondered whether an APM could be structured in a way that

reduces actuarial risk for providers but delivers value to payers and patients. One participant said, *"It's really not just about risk; it's about APM design and how the risk moves with that."*

> *"Hearing the different perspectives, it really does feel like there could be a path forward that decreases the amount of actuarial risk being taken on by providers but still brings value to payers, patients, and others. So I think that's an interesting direction.*
>
> —Subject matter expert

In addition to these priority topics, participants noted several other issues of interest for this group to continue to explore:

- A broader look at oncology in the context of APMs, including examples of oncology bundles that include surgical or radiation oncology
- APM models that empower both centers of excellence and community providers to have a sustainable role in the administration of cancer care
- Ongoing, robust analysis of what we are learning from OCM as an experiment
- Impact of emerging technologies like blockchain and telemedicine and trends like home-based care, and their implications for APMs
- Continued interest in quality measures and outcomes

Participants affirmed the ongoing need to exchange ideas and knowledge on APMs in oncology and complementary efforts as existing and planned pilots evolve. Some indicated that they would take what they learned in the meeting and use it to consider modifications to their models. One said, *"I really appreciated the talk on reinsurance today. We've talked about it [for our model] and I think I've learned a lot about that today that reshapes my view of what reinsurance can do for us."*

Participants affirmed that ongoing analysis of a variety of models is particularly important if they are to serve patients across the complex and diverse US healthcare system. A provider said, *"What works in oncology will not work in obstetrics. What works in New Mexico may not work in New York. We need to have the ability to vary."*

> *"A take-home message is that this project will never be done. It has to continually evolve because the science is continuing to evolve, and we will need different things in 2022 than what we need today."*
>
> —Provider representative

Finally, they emphasized the need for a continuous learning environment, given the dynamic landscape for innovation. One participant said, *"As we talk about value-based payment in oncology, we must always be aware that this landscape can literally change overnight. Imatinib made a disease that was almost uniformly fatal into a disease that has prolonged survival. That has to be built in and understood. Any payment model has to take flexibility and awareness into consideration."* In this spirit, the council will continue to discuss and refine the topics and questions raised in conversations to date in anticipation of their next meeting in early 2019.

About this document

This ViewPoints *reflects the use of a modified version of the Chatham House Rule whereby comments are not attributed to individuals, corporations, or institutions. Italicized quotations reflect comments made by participants before the meeting in individual and group calls or during the meeting.*

Tapestry Networks is a privately held professional services firm. Its mission is to advance society's ability to govern and lead across the borders of sector, geography, and constituency. To do this, Tapestry forms multistakeholder collaborations that embrace the public and private sector, as well as civil society. The participants in these initiatives are leaders drawn from key stakeholder organizations who realize the status quo is neither desirable nor sustainable and are seeking a goal that transcends their own interests and benefits everyone. Tapestry has used this approach to address critical and complex challenges in corporate governance, financial services, and healthcare.

Appendix: A case study on clinical data partnerships—an example for oncology APMs?

As noted above, some participants suggested that the current data business model needed to be upended. One recommendation was to establish partnerships whereby drug manufacturers pay providers for high-quality data entry and generation in exchange for access to the data. During the meeting, participants considered a case study from the field of genomics as a potential partnership model to replicate.

In 2014, Geisinger Health System and Regeneron Pharmaceuticals announced a collaboration to sequence and analyze the genomes of Geisinger patients.[30] The MyCode Community Health Initiative was the first clinical genome sequencing effort available to average Americans as part of standard primary medical care, and it has since sequenced over 200,000 individuals.[31] It aims to assess genetic determinants of disease, integration of genomics into clinical practice, and genomics' relevance to long-term health outcomes. Through the partnership, Geisinger was able to provide Regeneron access to its clinical EHR data, its biobank, and its sample collection processes while Regeneron supported the sequencing and analysis of Geisinger's patients.

As a result of the partnership, Regeneron has been able to use de-identified genomic data and a version of Geisinger's electronic health records for more than 90,000 patients to date for translational science purposes.[32] Since the initiation of the project, Regeneron has identified hundreds of novel candidate gene targets.[33] If Regeneron is able to successfully develop a drug based on MyCode data, Geisinger will receive royalties that will be reinvested in its nonprofit healthcare system.

In the meantime, patients who voluntarily opt in consent to being informed about genetic findings relevant to their health. Currently 85% of patients in MyCode have consented to this information and more than 500 individuals have received clinical reports informing them that they have a genetic variant.[34] With MyCode's success, Geisinger announced in May 2018 that it would now integrate genomics into standard preventive care for its patients, starting with a 1,000-patient pilot.[35]

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