



## Addressing how capital markets can expand access to oncology treatments

Many patients in the United States struggle with out-of-pocket medical expenses. For patients with cancer, who are more than twice as likely as their peers to declare bankruptcy, the financial costs are particularly acute.<sup>1</sup> In 2017 and early 2018, Tapestry Networks, in partnership with payers, pharmacy benefits managers, physicians, finance professionals, actuaries, and academics, launched the Innovative Healthcare Financing (IHF) initiative to address how financing vehicles could enable greater patient access to oncology treatments.

Earlier conversations with financial and healthcare professionals on financial approaches that could be applied within the US healthcare system to manage costs and expand patient access made clear that the respective groups did not speak a common language.<sup>2</sup> Therefore, the IHF initiative began with an educational call series to create a shared baseline understanding among participants of the US healthcare system, its product and financial flows, and its complexities specific to oncology.

The effort culminated in a November 2017 working meeting that was co-hosted by Dana-Farber Cancer Institute and aimed to build on the education series and existing conceptual thinking in this area.<sup>3</sup> The meeting's scope was targeted. While recognizing that long-term sustainability of the healthcare system will require significant systemic changes, participants focused on brainstorming interim solutions to meet an immediate need: the rising costs of oncology treatments and resulting gaps in access.

The group addressed how complex financial tools could be used in two areas that are in particular need of attention:

- Rising patient out-of-pocket costs
- The budget impact of high-cost oncology treatments on institutional stakeholders: payers, pharmacy benefits managers, and others (e.g., pharmacies, providers) within the supply chain

The following is a summary of the points raised during the meeting and other conversations throughout this effort.

## Patient out-of-pocket costs

Discussions centered on the desirability and feasibility of creating and implementing consumer financing programs as a way to address the challenge of rising out-of-pocket costs for patients.

### Is there a need for consumer loans in healthcare?

Participants discussed whether a consumer loan program might offer a better alternative to managing out-of-pocket medical costs than current vehicles such as high-interest payday loans or credit cards. The concept of consumer loans for patients is politically sensitive and may create public relations challenges, depending on who is providing the loans, how collections are handled, and the rates of loans provided.

However, medical debt is already a reality in the United States. A financial institution reported receiving as many as 50,000 applicants per month for loans relating to out-of-pocket medical expenses. Out-of-pocket costs for cancer, experts noted, can easily escalate to the annual out-of-pocket maximum mandated by the Affordable Care Act (ACA) of \$7,150 for individuals or \$14,300 for families.<sup>4</sup> Nearly two-thirds of American families cannot afford a \$1,000 unplanned expense, and more than 80% could not afford a \$5,000 expense, some participants said. *“Consumers are finding inartful ways to pay for treatment because they must. They go without food; they stop paying for education. They make meaningful sacrifices financially,”* one participant said.

Out-of-pocket expenses are a significant barrier to adherence in particular. Participants noted the abandonment rate for oral therapies at the pharmacy is approximately 30% when patients are faced with costs of \$500. In the absence of structural changes in the United States to reduce healthcare costs for patients, a loan product with a reasonable interest rate and repayment term could promote better adherence for patients who may otherwise choose to skip or stop treatments or take out high-interest debt.

Some participants noted that the solution to the above challenge might already exist. *“Health savings accounts [HSAs] were meant to be a vehicle to help out-of-pocket costs. They were portable, didn’t expire, and dollars were pre-tax. The idea was to save money to handle high-deductible plans with a vehicle that could be portable if you change employers or insurers. You could argue that many folks didn’t have the means to invest in an HSA, but from a vehicle perspective, it certainly was there and remains there.”* Participants asked whether HSAs could be restructured to be even more flexible—for example, by delinking them from high-deductible health plans so that more patients could contribute to them. However, the question remains whether patients and families would be able to contribute much at all.

Some participants noted that recent changes to components of the ACA may change the game entirely, opening a new era for even more out-of-pocket spending. The Trump administration’s October 2017 executive order ended restrictions on association and short-

term health plans;<sup>5</sup> therefore, some participants expect a proliferation of healthcare plans that do not offer the essential benefits requirements set by the ACA. One said, *“Association plans have changed the environment. Now healthcare is more local, nuanced, complicated, and more fragmented. Short-term plans are coming back to the forefront. Under the previous ACA framework, things were much more regulated. Now, it’s gotten more complicated; it’s gotten messier.”* Some experts and advocacy groups anticipate that association plans and short-term plans may significantly impact patients who develop cancer.<sup>6</sup>

### What would it take to make consumer financing programs a reality?

Participants explored how a loan program could be structured and what institutions would need to be involved or created to implement it. Discussions highlighted both loan securitization and subsidization.

Participants suggested financial institutions could develop ways to securitize loans to diversify complex risks associated with medical debt. *“Healthcare consumer loans are hybrid risks—mortality, credit, and so forth. You need somebody who can mass a variety of those risks and use diversification to make it a manageable pool of capital,”* a participant said.

Participants noted that any consumer loan program would need a degree of subsidization to make rates and terms manageable for patients. They discussed the role pharmaceutical manufacturers could play, proposing two subsidization models:

- **Single-manufacturer, single-drug model.** Drug manufacturers could subsidize the risk of a loan program associated with a single drug. This would allow for reduced interest rates and align the loan product with clinical outcomes. Through such a program, manufacturers would be able to expand treatments to a population that may not get access or might abandon their treatment pathway before it is complete. One stakeholder noted, *“All of us are interested in seeing the volume growth to the appropriate patients.”* The risk of subsidizing such a program would be negligible for a manufacturer because any additional access would yield incremental additional revenue from patients who would otherwise not be on treatment. In this model, the manufacturer would act as a backstop, guaranteeing the loans by linking them to their products’ successful outcomes, whereby unsuccessful treatments or death would cancel the debt.
- **Multiple-company, multiple-treatment model.** Participants discussed whether multiple manufacturers or other stakeholders could subsidize a portfolio of loans for diverse medical treatments that would be delivered by a third-party institution. This model could provide several benefits, including the opportunity to spread out financial and clinical risks for manufacturers and investors; the ability to offer a single blended interest rate to investors via securitized loan vehicles; and the potential ability to subsidize out-of-pocket expenses beyond treatment costs, such as travel, given the restrictions on manufacturers doing so.<sup>7</sup>

In addition to manufacturers offering or subsidizing loans, another participant suggested during post-meeting conversations that payers could play a similar role. *“Maybe there’s an opportunity for a payer or a plan to be sort of a lender, although this potentially may need to be regulated differently. There is opportunity for a structure where a payer can also serve as a lender in conjunction with a value-based design concept. This could result in lowering the cost of the insurance product to the plan member,”* the participant said. Such an approach would be similar in principle to that adopted by insurers, regulators, and financial institutions for the creation of HSAs.

A loan program may also require a special-purpose entity that could act as a neutral buffer between the companies that subsidize the loans and the patients, particularly in the pooled model described above. The special-purpose entity or institution could also play a role in assessing clinical risks. Some suggested that reinsurers were well positioned to help create or be a part of such an entity. This would not be part of their existing business but would instead represent an area for innovation within the industry, or, as one stakeholder described it, *“reinsurance 2.0.”*

Participants also discussed which patient populations might benefit most from a loan program. Patients with high-deductible plans or Medicare patients without supplemental coverage were likely candidates. Loans could also target lower-middle-income patients who fall above the income requirements of traditional manufacturer patient-assistance programs.

### **For what types of therapies would such a program work?**

Participants noted that a loan program must target treatments with strong efficacy, and/or *“clearly defined endpoints and biomarkers for response,”* for a financial institution to be willing to take the risk. They debated, however, the extent to which these therapies needed to be *“transformative”* or *“curative.”*

Transformative therapies, participants emphasized, would help mitigate any clinical uncertainty and therefore reduce risk and cost of capital. Furthermore, they underscored that a therapy that is *“one-and-done”* or involves a short course of treatment is easier to model than one requiring chronic, longer-term dosages.

However, transformative therapies might also pose several challenges, stakeholders noted. First, there is no neutral arbiter of what constitutes a transformative therapy. Participants suggested that the loan vehicle itself or a special-purpose entity could be the judge, given that it would closely examine risk and create and monitor other loan-related criteria. Second, some transformative therapies, such as chimeric antigen receptor T-cell (CAR-T) therapy, are personalized for each individual, raising questions about the potential scalability of any program that may be outcomes driven.

Participants also considered the value of a loan program for currently marketed specialty oncology products that are not one-and-done transformative therapies. They emphasized these products' high costs—in some cases, \$250,000 per year—which contribute to high out-of-pocket expenses for patients today. Participants also noted that cancer patients typically have high up-front costs associated with diagnosis, but then go on to longer-term, chronic treatments; they may also undertake a series of treatment cycles, the success of which can vary. Therefore, a loan program targeting existing treatments may help promote longer-term utilization and adherence, some emphasized.

### What questions remain?

Building from the above discussion, participants raised several overarching questions that would need to be resolved in order to make loans a viable and appropriate option for patients and pave the way for designing such a program:

- ? Should a loan program target the cost of treatment alone or other out-of-pocket needs, such as specialist consultations or travel? Industry participants noted the restrictions on pharmaceutical companies subsidizing copay assistance and other out-of-pocket costs for Medicare patients.
- ? For what types of therapies would a loan program be most appropriate? Is there greater value in such a program to support costs associated with a transformative therapy or existing specialty products? Would the specific therapy matter if the program was structured as a pool?
- ? Can stakeholders pinpoint the relevant populations and obtain sufficient demographic and financial data on them to allow for financial modeling on possible default rates? Could such a program also develop a mechanism that identifies early-stage patients (i.e., those with the greatest chance of clinical success and who have yet to incur out-of-pocket expenses)?
- ? Are there regulatory barriers from financial regulators? Stakeholders believe there are not, but this would require further confirmation.
- ? Can the loan program subsidize most (or all) of a patient's initial payments, given that the immediate postdiagnosis period is when patients and their families incur the greatest expense? Could this be structured so that patients would be charged zero interest up front?
- ? Are there other stakeholders who could play a role? Consider the following:
  - Employers or employer purchasing groups, who might be interested in offering subsidized financing options for their employees
  - Reinsurers or life insurers, who might have the appetite to subsidize loans, given they have a vested interest in keeping patients alive and on treatment

- Patient advocacy groups, working with third parties, who also might be willing to help subsidize up-front interest payments (participants noted similar precedents in existing patient copay assistance programs)

## Institutional stakeholders

Participants discussed how institutional stakeholders, including payers, pharmacy benefits managers, pharmacies, and providers, could mitigate the budget impact of high-cost oncology treatments.

### How might payers use capital markets to manage rising financial risks?

Participants addressed whether institutional stakeholders, particularly payers, could benefit from novel approaches that might reduce their financial risks or enhance underwriting. As new transformative, high-cost therapies are introduced, there could be a flood of up-front costs associated with adoption across a large population all at once, which could create short-term liquidity challenges for some payers.

However, some participants contended that this prospect may be overblown. Commercial payers have regulatory requirements that they keep a significant level of capital reserves, some of which could be drawn on to avoid liquidity issues. They are also able to increase premiums in subsequent plan years to recoup revenue and sustain their business.

Nevertheless, many participants acknowledged that continually raising premiums is not sustainable over the long run, and some have observed that for small- and medium-sized payers, high-cost specialty treatments are already *“driving them to the brink,”* as one participant said during post-meeting discussions. He elaborated: *“For plans in the small- to medium-sized space—for example, ones that cover one state, or one or two counties—these folks are not in leading-edge environments. They struggle with capital requirements and sophistication in insurance. If there’s a confluence of membership that requires specialty drugs, capital becomes an issue very quickly, and they need capital to satisfy regulators.”*

Participants noted that some payers are already considering amortizing high-cost treatments as one potential solution to the above issues. While patient portability to other plans has long had a chilling effect on amortization programs, some participants noted that payers are now more open to considering ongoing payments to the manufacturer, even after a patient leaves a plan, given that it is preferable to paying the full cost up front. Further discussion is required across a broader range of insurers and reinsurers to more specifically define the need in this area.

Finally, in conversations following the meeting, some participants suggested that payers involved in implementing Medicare Advantage plans have opportunities for innovation and flexibility offered by the Centers for Medicare and Medicaid Services’ recently expanded Value-Based Insurance Design (VBID) initiative.<sup>8</sup> *“I see an opportunity for a deeper dive with payers that could structure an insurance design that takes into consideration high-cost drugs.*



*Pharma companies could work with payers and reinsurers to mitigate costs and could also benefit payers with a reinsurance backstop. There may also be an opportunity for pharma to partner with reinsurers and take a holistic solution to a plan or payer,”* a participant said. While the VBID program does not focus on oncology, it could test new models for increasing quality and reducing costs associated with specialty treatment that could, in turn, inform the oncology field.<sup>9</sup>

### **Do providers or integrated systems need more sophisticated financial tools?**

Given the direction of innovative cancer treatments, providers are increasingly at risk for investments and costs required for delivery of care—for example, for a patient undergoing CAR-T treatment, providers are required to commit to having a hospital bed available for 30 days. Provider systems may require new financing vehicles that could provide liquidity and hedge relevant risks; however, efforts to explore this are nascent and would require further discussion as demand grows for complex immunotherapy-based care.

Some experts anticipate that the healthcare industry is on a path to more consolidation and vertical integration, with the pending CVS-Aetna merger being the foremost example.<sup>10</sup> Therefore, integrated companies and systems may need more sophisticated capital-management solutions to support increasingly complex risks. One participant said in post-meeting discussions, *“We do see an opportunity to support providers. As vertical integration starts to occur, many hospital systems are indeed looking to other partners, like reinsurance, for example. Vertical integration will require all the parties to come to the table. If we could package a solution for payers and maybe for vertical integration systems, there’s something there to talk about.”*

### **The way forward**

Achieving the vision of a US healthcare system that is affordable for patients, is sustainable for society, and enables access to best-in-class treatments will require significant debate and structural changes in the years to come. In the meantime, out-of-pocket expenses for cancer patients are increasing and creating financial toxicity today. The above exploration of a potential consumer loan program, while an imperfect approach, represents one way in which out-of-pocket costs could be more manageable within a one- to three-year time horizon.

Participants may want to further explore modelling such a program and its potential variations (i.e., a single-drug versus pooled approach) and further consider the key questions listed above. Stakeholders noted that a modelling phase would likely require data on the following:

- Size and demographics of the patient population
- Size of the loan
- Efficacy of the treatment, and distribution and durability of outcomes

- Cost of the treatment and/or estimates of out-of-pocket costs relative to the treatment
- Potential regulatory issues

On the institutional side, some participants recommended further exploration of partnerships across payers, manufacturers, and reinsurers to design new value-based insurance products. These could target small- and medium-sized payers that struggle with high-cost specialty products, such as oncology treatments, and may be less familiar with tools, such as reinsurance, that can help them better manage capital and costs and underwrite their insureds. These players could also design novel financial tools tailored to integrated or consolidated healthcare entities that may be taking significant medical risk in the oncology space in the future.

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Following the multistakeholder discussion, group members noted their optimism that *“different types of organizations can be pointed in the same direction”* and that the private sector could take the lead in addressing the critical question of *“patients having access to good therapies.”* A participant concluded, *“We have moved from sculpting fog to having a tangible approach that could be tested under the right boundaries to a pilot stage. This is worth pursuing.”*

### **About this document**

*ViewPoints* reflects the network’s use of a modified version of the Chatham House Rule whereby participants’ names and affiliations are a matter of public record, but comments are not attributed to individuals, corporations, or institutions. Italicized quotations reflect comments made by participants before, during, and after the meeting.

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## Endnotes

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<sup>1</sup> Helaine Olen, [“Even the Insured Often Can’t Afford Their Medical Bills.”](#) *Atlantic*, June 18, 2017.

<sup>2</sup> As was illustrated during a workshop on transformative therapies convened by leadership of Tapestry Networks, Dana-Farber Cancer Institute, and MIT Sloan School of Management’s Laboratory for Financial Engineering. [Workshop on New Financing Structures for Transformative Therapies](#), Summary of Themes (Waltham, MA: Tapestry Networks, 2016).

<sup>3</sup> Current conceptual thinking includes, for example, Vihad Montazerhodjat, David Weinstock, and Andrew Lo, [“Buying Cures versus Renting Health: Financing Healthcare via Consumer Healthcare Loans.”](#) *Science Translational Medicine* 8, no. 327 (2016).

<sup>4</sup> [“Out-of-Pocket Maximum/Limit.”](#) Healthcare.gov, US Centers for Medicare & Medicaid Services, accessed February 5, 2018.

<sup>5</sup> Robert Pear, [“Trump Proposes New Health Options for Small Businesses.”](#) *New York Times*, January 4, 2018.

<sup>6</sup> American Cancer Society Cancer Action Network, [Association Health Plans—Bad for Cancer Patients and Survivors](#) (American Cancer Society, October 13, 2017).

<sup>7</sup> Drug companies are prohibited from subsidizing co-payments and related out-of-pocket costs for patients enrolled in government healthcare programs like Medicare. Nate Raymond, [“IRS Probes Drug Company-Funded Patient Assistance Charity.”](#) *Reuters*, June 29, 2017.

<sup>8</sup> Centers for Medicare and Medicaid Services, [“Medicare Advantage Value-Based Insurance Design Model \(VBID\) Changes for CY2019.”](#) news release, November 22, 2017.

<sup>9</sup> Centers for Medicare and Medicaid Services, [“Medicare Advantage Value-Based Insurance Design Model \(VBID\) Changes for CY2019.”](#)

<sup>10</sup> Carolyn Y. Johnson, [“Pharmacy Giant CVS Is Near a Deal to Merge with Aetna.”](#) *Washington Post*, December 1, 2017.