Summary

As treatment advancements in oncology continue, stakeholders are modifying their approaches to defining value and managing care.

Recent advances in cancer treatment represent significant scientific developments that are likely to fundamentally change oncology care in the US. While such advancements provide clinical promise for cancer patients, they also contribute to increased healthcare spending. In parallel, stakeholders must adapt to the realities of the COVID-19 pandemic which has created barriers on access to care for oncology patients and necessitates changes to the healthcare delivery landscape.

In response, healthcare stakeholders are reframing traditional care management strategies to balance cost, access, and quality of care in an evolving oncology market.
New and Emerging Therapies

This is a pivotal moment in oncology. Researchers and manufacturers are developing more sophisticated therapeutic options that involve novel diagnostic techniques, delivery mechanisms (e.g., viral vectors), and therapeutic regimens.

Notable advancements include:

**Advanced Diagnostics:** With the goal of providing individualized treatments, precision medicine often relies on genomic sequencing to identify biomarkers that may indicate an appropriate target for certain therapies. The use of biomarker tests has increased greatly over the past two decades: between 2000 and 2018, the use of biomarkers in all oncology clinical trials grew from 15% to 55%. Moreover, as of 2019, 66% of oncology patients receive a biomarker test, which helps guide providers’ ability to select appropriate treatments.

**Combination Therapy Regimens:** Clinical evidence increasingly indicates that combination therapies—regimens which employ several cancer drugs simultaneously—may be more effective than single treatments alone. Given that the percentage of US patients with cancer eligible for these therapies grew from less than 2% in 2011 to nearly 44% in 2018, these treatment regimens are expected to become more prevalent in cancer care.

**Cell and Gene Therapies:** Among the newer treatment modalities to emerge in oncology, cell and gene therapies, such as CAR-Ts, offer potentially curative solutions to complex diseases. Fifteen to thirty durable cell and gene therapies are expected to launch in the US over the next 5 years. The high up-front cost of these therapies can present challenges to providers, payers, and
patients, including substantial short-term budget impact, uncertain therapeutic durability, and inadequate reimbursement. Recently, CMS proposed to create a new Medicare Severity Diagnosis-Related Group (MS-DRG) for CAR-T treatment stays to address concerns around Medicare’s CAR-T inpatient reimbursement.

As manufacturers continue to invest in development of oncology therapies, they will have to consider how the pandemic may impact their ability to effectively run clinical trials as well as put in the right supply chain infrastructure and distribution models to support new product launches necessary for innovative therapies.

**Managing And Paying For Emerging Therapies**

Parallel to the continued innovation in the oncology market, stakeholders are restructuring the traditional role of the payer, with significant implications for the management and payment of oncology care.

**Shifting Risk to Providers via APMs:** To incentivize overall reduction in cost of care while maintaining high quality, more payers and providers are entering into joint risk-sharing agreements. In 2018, 55% of oncology practices reported participation in an APM.

Catalyzing this transition, CMS has piloted some of the more well-known APMs, such as the Oncology Care Model (OCM), and has recently proposed the Oncology Care First (OCF) Model and Radiation Oncology Model. Practices participating in the OCM are increasingly entering into down-side risk arrangements, with a recent Community Oncology Alliance (COA) survey finding that over one-third of respondents plan to remain in the OCM and enter into two-sided risk. Private payers are also exploring implementation of APMs (e.g., Aetna, UHC) focused on improving care coordination and reducing total cost of care.

Yet as stakeholders consider the transition to more advanced total cost of care models, they will have to closely monitor the changes in expenditure patterns associated with COVID-19. Based on a recent Avalere analysis, the pandemic is likely to have a differential impact on OCM practices based on their region. Accordingly, CMMI may have to consider adjusting the OCM methodology as well as the timeline for the transition into OCF and downside risk arrangements.

**Care Delivery and Coordination:** The pandemic has created notable limitations on in-office visits. According to a recent Avalere analysis, the volume of chemotherapy infusion services dropped by 33% between April 2019 and April 2020. In response, stakeholders are seeking new solutions to effectively deliver and manage care remotely. Specifically within Medicare FFS, new
federal rules have created flexibilities to expand coverage to telehealth and home infusion services.

In the commercial space, the five largest payers have all integrated a pharmacy benefit manager (PBM, i.e. Aetna/CVS Health, Cigna/ESI, Humana/Walmart, United/OptumRx, and Anthem/IngenioRx) and are increasingly moving into the care delivery space. Amid the pandemic, such integration could enable payers to offer new solutions to manage patients across alternative sites of care including pharmacy storefronts, infusion centers, and the home.

Further, manufacturers and third-party patient support programs have an opportunity to enhance service offerings and hub models to support patients’ evolving needs. As stakeholders get accustomed to more remote approaches, this could create avenues for expansion of flexibilities beyond the pandemic.

**Enhanced Decision Support:** As new treatment options emerge and the availability of clinical trials grow, providers and payers are relying on treatment support tools to make informed decisions. The growing availability and sophistication of clinical-decision resources creates opportunities to streamline utilization management processes between providers and payers. The evolution of prior authorizations via ePortals or provider attestation of attributed patients within episodic payment models represent key examples of more automated means to replace or supplement traditional payer-driven utilization management. Additionally, providers are developing their own order sets and clinical pathways and, in some instances, making them available to other oncologists (e.g., Philips IntelliSpace Precision Medicine Oncology Pathways powered by Dana-Farber).

In addition, growth in shared decision making tools and expansion of patient-reported outcomes (PROs) into routine and specialty care could enhance the patient experience. For example, CMMI announced its intention to integrate ePROs into the OCF Model to inform quality measurement and enhance care coordination.

**Paying for Outcomes:** Manufacturers, payers, and providers are entering arrangements that tie product reimbursement to clinical, quality, utilization, or financial outcomes. Avalere survey data shows that between 2017 and 2019, the percentage of payers reporting to have executed an outcomes-based contract increased from 24% to 59%. More recently in oncology, the emergence of short-term and high-cost treatments offering a potential cure (e.g. cell and gene therapies) has reinvigorated the push for novel payment approaches. In response, stakeholders are exploring new value-based payment mechanisms such as annuity or installment payer models in which payment for therapies is spread out over a prolonged period of time and is tied
to outcomes.

Therapeutic and financial management shifts will continue to shape the oncology market over the next few years. Stakeholders must work together to ensure alignment across diagnosis, treatment decision-making, and reimbursement so that best-in-class treatment for cancer patients remains accessible and affordable.

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