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ONCOLOGY TREATMENT ACCESS IN 2020 AND BEYOND

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2020 promises to be eye-opening, as the coming election will surely provide clarity to the path that we will be taking for oncology treatment access. From international reference pricing, acceleration of biosimilars and generics, and allowance of reimportation, pressure continues to mount to reduce pharmaceutical prices—especially those used to treat cancer. Much of the year will be focused on aligning misaligned incentives. Even now there are several proposals that could form the foundation for this future landscape impacting oncology treatment access.

Part of this foundation is based on the House passage of legislation this past December to reduce prescription drug prices by giving the federal government the ability to negotiate prices with drugmakers for a minimum of 50 and up to 200 drugs per year. While the Elijah E. Cummings Lower Drug Costs Now Act will likely fail to pass the Senate, its passage will put pressure on the Republicans to pass meaningful reforms, which will likely be included in a 2020 Senate package. Drug pricing will be a differentiator for voters in the 2020 election.

Beyond these direct pricing pressures there is also work to realign previous misaligned incentives. With fee-for-service (FFS) still the dominant revenue source for most providers, this payment for each service rendered is vulnerable to misuse and overutilization with no incentive to consider cost. Neither the patient nor the provider "feels" the cost of the service offered with the result being promotion of overuse of medical services with high levels of spending. This is the major driver for value-based care where providers are being held responsible for the total cost of care.

Buy and bill pays providers a positive percentage on the drug costs, which could favor the use of higher cost treatments. The new Centers for Medicare and Medicaid Services (CMS) rules mitigate this incentivized reimbursement strategy in a subset of enrollees by allowing Medicare Advantage (MA) plans to manage Part B drugs through step therapy. This permits MA plans with the opportunity to encourage the use of their preferred agents.

> "Pressures on pricing and access for oncology treatments will increase in 2020. Winners in this space will be those that articulate their value to key stakeholders and that support developing new channels for diagnosis and treatment."

There are existing mechanisms to align incentives that include new technology add-on payment (NTAP), used by Medicare to reimburse hospitals for infusing new therapies with evidence of clinical improvement from previous therapies and that are inadequately paid for under current diagnosis-related group (DRG) payments. NTAP does not require novel drugs and devices to be used for their FDA-approved indication. This is an attempt to prevent underutilization of therapies that are not accounted for in the DRG while the prospective payment system recalibrates to reflect the cost of a new technology.

Quality measures are another mechanism used by Medicare to make sure diagnostics and medications are appropriately utilized even though plans have traditionally been reimbursed by Medicare through a capitated rate based on patient risk profile. Medicare Advantage star ratings are based on over 40 quality measures that ensure plans are providing adequate preventative screenings and vaccines, managing chronic conditions, enrollee satisfaction, and timely appeals. Enrollees can see star ratings when choosing a plan and most enrollees choose plans with at least 4 stars. Additionally, the Affordable Care Act created quality bonus payments for Medicare Advantage plans that achieve at least 4 stars to incentivize plans to appropriately utilize tests and treatments.

Another alignment of incentives is the use of Clinical Decision Support Mechanism (CDSM) to assure appropriate utilization. Beginning in 2020, Medicare Part B advanced diagnostic imaging services will be judged based on appropriate-use criteria, which are grounded in established clinical pathways. While this applies to all advanced diagnostic imaging services, it will likely be especially significant for oncology care, given the reliance on this type of diagnostics in cancer management. Failure to follow these clinical pathways—which could result in overutilization especially favored by providers that have a financial stake in these diagnostic tests—could result in CMS crawling back funds as a means of enforcing

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best clinical practice application. This will impact the diagnosis and tracking of many cancers and has the potential to impact treatments, as well.

Finally, and again in December 2019, the Senate Finance Committee released a revised Prescription Drug Pricing Reduction Act that imposes a "site-neutral" cut to drug administration services furnished at exempted off-campus locations (ie, 40% of the outpatient prospective payment system rate) starting January 1, 2021. This would eliminate the financial incentive for health systems to limit infusion treatments at hospital-based sites of care and caps the add-on payment that results from the average sales price (ASP) plus 6% formula, limiting the value of the plus 6% to $1000. This, combined with efforts to eliminate buy and bill, would remove incentives for oncologists to utilize office-based treatments.

Bottom line – 2020 will see increasing pressure on pricing and access for oncology treatments as the government focuses on reducing costs. Winners in this space will be those that not only articulate their value to key stakeholders but also support the new channels that will develop for diagnosis and treatment. Many of these channels will be new to this market with different incentives and delivery systems, making 2020 look and feel very different than anything we have ever seen before.

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