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New Payment Models For Cell, Gene Therapies Unlikely To Originate With Medicare – Former Official

by Cathy Kelly

Risk-averse decision-making climate at CMS and a likely unwillingness to commit the resources needed probably means that innovative payment arrangements for cell and gene therapies may have to start in the commercial insurance sector, Demetrios Kouzoukas suggests.

The most effective way for cell and gene therapy innovators to help advance innovative payment models in Medicare would be to develop such arrangements in the private sector and then bring results to the Centers for Medicare and Medicaid Services for possible adaptation, according to former Medicare director and CMS principal deputy administrator Demetrios Kouzoukas.

"Private payer examples of successful value-based arrangements would be incredibly helpful to CMS," Kouzoukas told the American Society of Gene and Cell Therapy annual policy conference on 22 September. "There's always this worry at CMS that because they're so big ... you kind of set the future by doing a pilot, and you didn't necessarily intend to do more than experiment," he explained.

Kouzoukas, who was also previously a principal deputy secretary at the Health and Human Services Department, is now a board member at Clover Health, a healthcare technology company focused on Medicare Advantage coverage.

The decision-making climate at CMS is cautious, he said. "It's hard to overestimate the difficulty of making decisions in advance. ... You've also got these very different scenarios that might be presented by different patient

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populations or different disease states and when CMS acts, it has to create general rules, and they don't fit in certain situations."

That "creates a cycle where it's really hard for the agency to be proactive," Kouzoukas continued. "It may, just as a procedural and fact-of-life matter, be preferable to wait until you understand exactly what patients are affected, when and how, and then race as quickly as you can within the regulatory process to adjust."

By Cathy Kelly

21 Sep 2021

Only about one-quarter of the 40 gene therapies projected to launch by the end of 2025 would have potential US patient populations of more than 50,000. But a handful of treatments could target millions of individuals.

Read the full article here

In light of that "I would encourage innovators to really think about when you could team with private payers around interesting arrangements and to provide those as models that give more information to CMS," he reiterated. (Also see "*New Payment Models For Curative Treatments Have CMS' Attention, Verma Says*" - Pink Sheet, 23 May, 2019.)

Kouzoukas also suggested the agency could benefit from data derived by developers from various clinical settings, such as inpatient and outpatient, because Medicare has different payment systems across those settings and tends to keep information in silos.

"The payment system is siloed, that's just a fact of life in Medicare fee-for-service, so data around the efficacy of these treatments in different clinical settings would be helpful from a demonstration standpoint and also coverage, which hasn't been as much of an issue for CAR-T therapy but might for other cell and gene therapies," he said.

Cost To Program May Not Justify Resources Needed

CMS and the Center for Medicare and Medicaid Innovation may not have the "bandwidth" to commit resources to developing new payment models for a class of treatments that while pricey, are still a relatively small cost to the program, Kouzoukas noted.

"They've got a set of tools to use, which is the demonstration authorities to run pilot projects and do value-based arrangements … but the bandwidth to do that is relatively narrow. There's a limit to the number of staff, the amount of time, the priorities and attention that you take from all the people involved, from legal and other parts of the executive branch, to get these regulations and these demonstrations out."

At the same time, "even though there is a high unit price tag for these therapies, the overall

dollar amount in the Medicare spend has been relatively low overall. I think that's part of why you haven't seen a demonstration [on paying for cell and gene therapy] to date. The focus at CMMI has been to try and move the dial around the big areas of need." (Also see "*New Medicare Payment Models Should Not Be All About Saving Money, CMMI's Fowler Says*" - Pink Sheet, 13 May, 2021.)

Medicaid A 'Promising' Area For Innovation

With regard to prospects for value-based arrangements in Medicaid, Kouzoukas said he has "high hopes" but that there are ongoing challenges. (Also see "*Drug Pricing Reform In Medicaid: Watch This Space*" - Pink Sheet, 10 Mar, 2021.)

"In Medicaid you have opportunities and challenges of 50 different platforms so from a federal level, what you're likely to see in any Administration is a desire to facilitate states to provide greater access," he said. Some rules of the road, including Medicaid best price reporting, have been identified as obstacles to such agreements and some progress has been made addressing them, he noted.

But he also said the "biggest challenges" arise in the process of actually negotiating such arrangements, when "lawyers, doctors and economists are trying to decide what the right measures are" to evaluate outcomes. "Until there is greater progress in having commonly accepted outcomes or measurements, it's hard to see progress in the value-based space," he acknowledged.

Nevertheless, "because of the cost of these therapies, and the possibility that each state can approach it differently, I think that Medicaid is a really promising area where that can play out."