

# More Drug Cost Initiatives: CMS Updates Drug Pricing Models for Cell and Gene Therapies and Accelerated Approval Products

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Last October, President Biden issued an executive order directing the Department of Health and Human Services (HHS) to consider actions to drive down prescription drug costs. In particular, the executive order directed HHS to consider whether the Centers for Medicare & Medicaid Services Innovation Center (CMS Innovation Center) could test new healthcare payment and delivery models “that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care.”

In response, and as discussed in a prior [Sidley Update](#), HHS [announced](#) that the CMS Innovation Center would test the following new payment and service delivery models: (i) a Cell and Gene Therapy (CGT) Access Model, (ii) an Accelerating Clinical Evidence (ACE) Model, and (iii) a Medicare \$2 Drug List Model.

Recently, CMS issued an [update](#) on the development of these models, reaffirming the important implications these models may have for CGTs, Part B drugs approved through the Accelerated Approval Pathway (AAP), and generic prescription drugs covered under Part D.

## **CGT Access Model**

The CMS Innovation Center announced that it is accelerating the development of the CGT Access Model “[t]o meet the imminent need expressed by states.” The CGT Access Model is a voluntary initiative that would allow state Medicaid agencies to participate in multistate outcomes-based agreements (OBAs) with manufacturers of cell and gene therapies. While the CMS Innovation Center previously announced a plan to launch this model in 2026, the agency now intends to launch the model in 2025, with rolling start dates for states to join the model. In discussing this model, CMS notes that the pipeline for CGTs “has expanded rapidly” since HHS selected this model for testing by the Innovation Center earlier this year.

Under the CGT Access Model, state Medicaid agencies would have the option of assigning CMS to structure and coordinate multistate OBAs with participating manufacturers instead of pursuing individual

agreements. CMS would then take on the responsibility of implementing financial and clinical outcome measures agreed on in the OBAs, reconciling the data, and monitoring and evaluating the results. The CMS Innovation Center is evaluating multiple conditions for inclusion in the model, including treatments for sickle cell disease.

The CGT Access Model presents an opportunity for CGT manufacturers to partner with CMS and states to demonstrate the value and effectiveness of their products and potentially reduce the administrative burden and uncertainty of negotiating and implementing multiple OBAs. While this could significantly impact Medicaid utilization, particularly for pediatric CGTs, by facilitating wider and quicker Medicaid coverage, it may do so at a significantly lower price, given the leverage of multistate agreements. The model could also enhance the generation and use of real-world clinical data, which is crucial for understanding the long-term impact of these therapies on patient outcomes and health equity.

The CMS Innovation Center is currently engaging with various stakeholders, including patient groups, clinicians, professional societies, federal agencies, states, and manufacturers, to gather feedback and input on the model design and implementation.

### **ACE Model**

Second, the CMS Innovation Center is developing the ACE Model, which would test the impact of Medicare Part B payment adjustments to providers for drugs approved via the AAP Program as a method to encourage timely completion of confirmatory trials by manufacturers of drugs approved based on surrogate or intermediate endpoints.

The ACE Model would apply to Part B drugs approved through the AAP Program. In its recent update, CMS notes that “more than 90% of accelerated approvals for Part B drugs over the past five years were for oncology indications,” although this model could also include drugs with accelerated approval for other indications. CMS further indicates that based on its analysis in partnership with the FDA, “only a small number of [AAP] drugs have experienced long delays” in completing confirmatory trials. CMS adds that the cases of delays “are often drugs approved for orphan indications where no alternative treatments are available, making enrollment in confirmatory clinical trials difficult once the drug receives marketing approval.” Even so, CMS states that feedback “from the FDA and interested parties, including patient groups, providers, and manufacturers, has suggested that there is an opportunity for a model that would test ways to encourage completion of confirmatory trials.”

The CMS Innovation Center has not articulated the precise method for adjusting Part B payments under the ACE Model, making it difficult to predict the precise impact of the model. Depending on the specifics of the payment adjustments adopted by the agency, the model could have significant implications for manufacturers of Part B drugs approved through the AAP and affect manufacturer incentives for conducting confirmatory trials. If the ACE Model significantly reduces Part B payments for AAP products, the model could also affect the prescribing behavior of providers and raise concerns regarding access and affordability of AAP drugs for Medicare beneficiaries.

The CMS Innovation Center is currently reviewing data and feedback from the FDA and other stakeholders on the model design and feasibility. The Innovation Center has not announced a launch date for the ACE Model but has stated that it intends to continue to monitor developments and trends in the AAP Program, such as the mix of products entering the AAP.

## Medicare \$2 Drug List Model

Third, the CMS Innovation Center is working on a Medicare \$2 Drug List Model, which would allow Part D plan sponsors to offer a low, fixed copayment (up to \$2 per month supply) for a standard Medicare-defined list of generic drugs across all cost-sharing phases of the Part D drug benefit up to the out-of-pocket limit. CMS states that this model aims to improve beneficiary access and adherence to low-cost generic drugs for common chronic conditions while reducing out-of-pocket costs and utilization management requirements.

The CMS Innovation Center states that its goal is to include in the \$2 Drug List Model approximately 150 generic drugs that “would offer a treatment option in over 90% of instances when a drug may be prescribed to a beneficiary.” It further states that it “expects the model to serve as a natural complement to” the changes to the Part D benefit design under the Inflation Reduction Act, which it estimates “will reduce out-of-pocket costs for approximately one-third of Part D beneficiaries by about \$400 annually.”

The \$2 Drug List Model could have a limited impact on manufacturers of generic drugs, as it would primarily focus on drugs already on lower-cost formulary tiers. However, the model could affect the market share and competition among generic drugs as well as the demand and pricing of brand-name drugs. The CMS Innovation Center states that it is currently conducting analyses and engaging with interested parties to understand the factors influencing the potential participation and impact for this model. It has not announced a launch date but states that “CMS will release additional details about this model as soon as is feasible.”

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CGT manufacturers, manufacturers of Part B drugs approved through the AAP Program, and other innovator companies, as well as additional stakeholders, should take note of these developments and consider the potential implications of these models. As the CMS Innovation Center seeks stakeholder feedback on the models, manufacturers and other interested parties should consider whether it is appropriate to conduct proactive outreach. Please contact your Sidley attorney or the authors of this update with questions.

## CONTACTS

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

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