

UPDATES

Cell and Gene Therapies Access Model on Sickle Cell Disease Announced by U.S. CMS Innovation Center

February 6, 2024

The U.S. Centers for Medicare & Medicaid (CMS) Innovation Center has announced that as part of the Cell and Gene Therapy (CGT) Access Model (first announced in February 2023), the agency will advance outcomes-based agreements (OBAs) between manufacturers and state Medicaid programs focused on CGTs for the treatment of sickle cell disease (SCD). Under the model, CMS will negotiate OBAs with participating manufacturers that will tie product pricing to positive outcomes for Medicaid patients. In exchange for manufacturers' paying model-negotiated rebates to the states, the states will implement an agreed-on standard access policy. Eligible manufacturers will be able to apply to the model by responding to a request for application (RFA) by May 2024, and negotiations will take place May through November 2024.

Details regarding the negotiation process and related requirements have yet to be published. The model may operate for up to approximately 11 years, depending on the OBA term for each state.

Background

The CGT Access Model's focus on SCD stems from the CMS Innovation Center's February 2023 announcement to test three new payment and service delivery models in response to President Joe Biden's October 2022 [Executive Order 14087](#): (i) a CGT Access Model, (ii) an Accelerating Clinical Evidence (ACE) Model, and (iii) a Medicare \$2 Drug List Model.

As discussed in a prior [Sidley Update](#), CMS issued an [update](#) on the development of these models in October 2023, reaffirming their importance and announcing the acceleration of the CGT Access Model in response to new cell and gene therapies and the imminent need expressed by states.

More recently, CMS [announced](#) that the CGT Access Model will focus its attention on SCD and [outlined](#) the model's purpose, eligible participants, population, and application process and rollout, described below.

CGT Access Model Purpose

The CGT Access Model is a voluntary initiative that will allow state Medicaid agencies to participate in multistate OBAs with manufacturers of certain CGTs in order to obtain discounted pricing, condition the

cost of CGTs on patient outcomes, and shift the burden of administering complex OBAs from individual state Medicaid agencies to CMS. The model aims to improve health outcomes and reduce healthcare costs for people in the U.S. who may benefit from CGT treatment.

CGT Access Model Participants

The model will involve CMS, participating states, and participating manufacturers. All states and territories that participate in the Medicaid Drug Rebate Program (MDRP) are eligible to join the model, subject to certain requirements. Manufacturers that market FDA-approved or -licensed gene therapies for severe SCD and participate in the MDRP can apply to participate in the model.

CGT Access Model Patient Population

The model population includes Medicaid primary payer beneficiaries and Medicaid expansion Children's Health Insurance Program (CHIP) beneficiaries who have SCD and receive an FDA-approved CGT for SCD. The model also allows for the inclusion of separate CHIP beneficiaries who have SCD and receive an FDA-approved CGT for SCD. The model targets more than 100,000 CHIP and Medicaid beneficiaries living with SCD who face high rates of health complications and costs and limited treatment options.

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CMS' focus on SCD presents a critical inflection point in the agency's position on outcomes-based arrangements and a potential opportunity for manufacturers of SCD therapies to work with CMS and state Medicaid programs to improve access to their therapies. However, it will be critical to monitor agency guidance regarding the application, participation requirements, and negotiation processes to understand the full implications of the model, which will run up to 11 years. Furthermore, manufacturers of cell and gene therapies in other therapeutic areas should take note of these developments and carefully consider the potential implications of this model as guidance continues to unfold. Please contact your Sidley attorney or the authors of this alert with questions.

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