

Domain 5 Findings - CMS Innovation Center's "Cell and Gene Therapy Access Model"

Background: In February 2023, CMS <u>announced</u> the Innovation Center would develop a <u>Cell and</u> <u>Gene Therapy Access Model</u>. According to CMS, this model would "establish a partnership among CMS, manufacturers and state Medicaid agencies, and it would test a new approach for administering outcomes-based agreements (OBAs) to help Medicaid beneficiaries gain access to potentially life changing, high-cost specialty drugs." Under this Model, "in lieu of state Medicaid agencies pursuing manufacturer agreements individually, state Medicaid agencies would have the option of assigning CMS to structure and coordinate multi-state OBAs with participating manufacturers." CMS said the agency "would also take on the responsibility of implementing, monitoring, reconciling, and evaluating the financial and clinical outcomes outlined in the OBAs."

In January 2024, CMS <u>announced</u> that the first model will address SCD. In December 2023, the <u>FDA</u> <u>approved</u> two gene therapies for the treatment of SCD. While CMS originally "envisioned that this model would launch in 2026," the agency <u>noted</u> that "to meet the imminent need expressed by states, the Innovation Center is accelerating model development and aiming for rolling launch dates with states joining the model throughout 2025."

Based on the information publicly available at the time of the survey, respondents identified model design features and processes for engaging the SCD community that should be included in the forthcoming CMS Innovation Center model to be attractive to state Medicaid directors in a manner that ultimately helps to effectuate timely access to any approved gene therapies for SCD. Responses are summarized below.

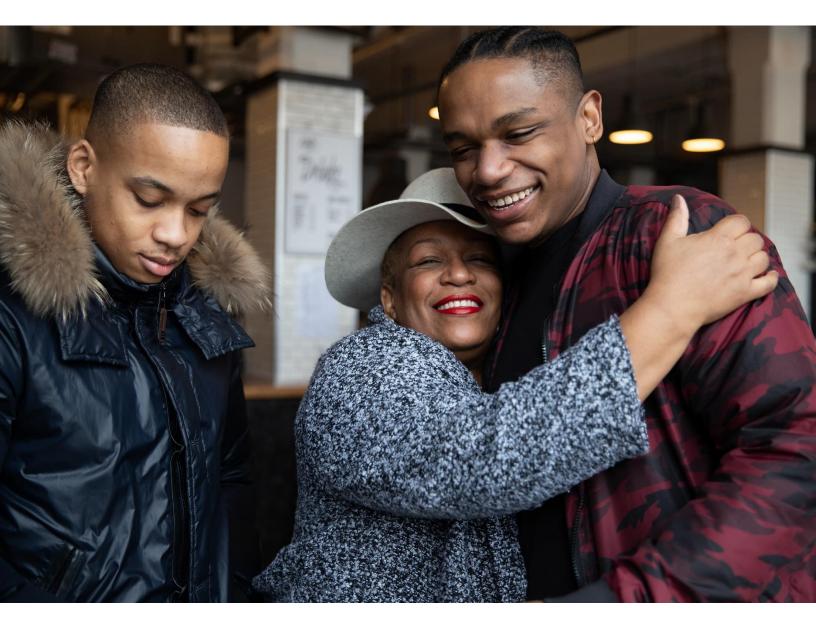
- A majority of respondents highlighted that coverage and payment design considerations are critical. Suggestions relayed by respondents included:
 - Creating a payment model that simplifies reimbursement for providers and Medicaid agencies, including potentially a per-member, per-month (PMPM) amount. This could be paid by the agency or an MCO to a center delivering care and a state plan amendment template to make it easy to implement.
 - Addressing the fiscal impact of gene therapies, which several respondents stated is the most substantial challenge.
 - Ensuring value-based outcomes are transparent, clearly defined, and able to be measured without ambiguity.
 - Enabling a better understanding of payment, quality measures (inpatient measures that we normally use should be tailored), and eligibility.

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- Covering services such as peer supports, family supports, community health worker care, etc.
- Ensuring states retain utilization management authority.
- A majority of respondents highlighted that the input of the SCD community of patients, families, community-based organizations, and providers in a state will be important for success. Other recommendations included:
 - Gather input and comments from the SCD community, as that work can be resource intensive for some states.
 - The SCD community and providers need to be actively engaged in reviewing the Model to ensure that any design elements do not lead to unintended barriers to access in states.
 - The evaluation component of the Model should be designed to incorporate feedback from actual Medicaid enrollees impacted by the model as well as SCD-related community-based organizations.
 - State Medicaid programs could form an advisory board of individuals with SCD, SCD care providers, and others to help inform state decisions.
 - Continue public testimony and comment are at applicable P&T, Drug Utilization Review, and Medical Assistance Advisory Council meetings as well as prior to posting of any final coverage bulletins.
 - The SCD community should attend budget hearings to advocate for the funds needed for treatment.
- Several respondents highlighted some of the structural considerations states face with respect to Model participation, including:
 - The structural differences of state governments' annual budget cycles compared with federal multi-year policy visions and the resulting tension as to whether a federal solution fits into a state's timing considerations.
 - Specialty models for rare disease may have limited appeal compared to other models that are targeted to broader-based diseases – despite the economic burden and impacts of the disease.
 - It will be important for CMS to allow for receiving comments and incorporating state feedback during the model design process.
 - Administrative barriers should be minimal if CMS wants states to adopt the model.
 - To build support for the Model, CMS should conduct advance work with larger MCOs and Medicaid Management Information System vendors in fee-for-service states.
- The vast majority of respondents said it is "very important/important" to Medicaid directors that the forthcoming Innovation Center Model include support for medical follow-up care and ancillary services related to gene therapy treatment. No respondents said this consideration was unimportant.

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• The vast majority of respondents said it is "very important/important" to Medicaid directors that the forthcoming Innovation Center Model include support for supportive social services to address needs like transportation, lodging, childcare, etc. for individuals receiving gene therapies. Multiple respondents said it was "somewhat important." It was also suggested that states adopt customized disease management or "navigation" services specific to SCD.



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