

State Letter of Intent

Thank you for your interest in the Cell & Gene Therapy Access Model (the Model). Any state, the District of Columbia, or U.S. territory that participates in the MDRP is eligible to participate in the Model.

Please complete this non-binding Letter of Intent (LOI) to help us better understand your interest in the Model. Information from the LOIs helps the Center for Medicare & Medicaid Innovation (Innovation Center, or CMMI) better understand state goals and challenges in applying to the Model so that we can facilitate a smooth application process. Information gathered through this LOI may also inform negotiations with manufacturers of cell and gene therapies for outcomes-based agreements.

While you are encouraged to submit an LOI, this form is not required to apply for participation to the Model at a later date. States will have the opportunity to review the key terms of an outcomes-based agreement negotiated between the Innovation Center and manufacturers, and to join or decline to join at that time. More application details will be available at a later date.

Please submit the complete LOI in PDF or Microsoft Word format to CGTModel@cms.hhs.gov by no later than 11:59pm EDT on April 1, 2024. Please direct any questions regarding the Model or this LOI to CGTModel@cms.hhs.gov. All questions are required unless marked otherwise.

Part 1: Administrative Background

1. Provide the name of your state.
2. Provide the name of your agency.
3. Provide the name and contact information for the person who CMMI should contact if there are questions or comments about your LOI.
 - a. Secondary Contact (optional)
4. Please indicate if you are participating in any other CMMI models.

Part 2: State Interest

5. What interests you in this Model?
6. What are your top priorities or goals that you hope to achieve in participating in this Model? (optional)
7. Please indicate if there is any state legislation that may interfere with participation in this Model, or require CMMI to make allowances in contracts to accommodate? (optional)

Part 3: Cell & Gene Therapy (CGT) Policies

8. Does your state have experience with outcomes-based agreements, supplemental rebates, or value-based purchasing arrangements?
 - a. If so, please briefly describe.
9. Does your agency have any specific payment policies for CGTs? (i.e., carved out of bundled payments, etc.)? (optional)
10. Please briefly describe the role of managed care organizations in providing access to high-cost therapies in your state. For example, do you utilize reinsurance or risk corridors? How do you align high-cost payment policies between managed care and fee-for-service populations? (optional)
11. Please describe your state's process for annual updates of your Preferred Drug List (PDL), including timing and update deadlines, and any collaborations with multi-state purchasing pools. (optional)
12. States may choose to include only their Medicaid population in this Model, or they may choose to include both their Medicaid and Title XXI CHIP populations. Title XXI CHIP populations will require an additional waiver of average sales price (ASP) calculations and a contract through the multiple best price pathway. At this time, does your state intend to: (optional)
 - a. Participate with only Medicaid beneficiaries?
 - b. Participate with both Medicaid and CHIP beneficiaries?
 - c. Unknown.

Part 4: SCD

13. CMMI is conducting its own analysis of Medicaid beneficiaries with SCD. However, we are interested in comparing and supplementing our analysis with data directly from states. If available, please provide the following information about individuals with SCD in your state (optional):
 - a. What is the total number of Medicaid beneficiaries in your state who have SCD? How many are in fee-for-service vs. managed care?
 - b. Please estimate the expected number of covered Medicaid beneficiaries in your state who will receive CGT per-year.
 - c. How many covered Medicaid beneficiaries in your state with SCD also have coverage through another payer (please separately enumerate beneficiaries for whom Medicare is the other payer and beneficiaries for whom a commercial payer is the other payer)?
 - d. How many covered Medicaid beneficiaries in your state with SCD are covered through a separate CHIP program?
14. The manufacturers of gene therapies for sickle cell disease have published lists of transplant centers that offer administration of their respective gene therapies, [here](#) and [here](#). If there are no transplant centers in your state, please describe your plan, if any, for ensuring adequate access to CGT for SCD.