(Insert Logo)

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

As members of the Personalized Medicine Caucus and members invested in ensuring that high value next generation therapies are available to patients, we write to acknowledge the recent activity by the Center for Medicare & Medicaid Innovation (CMMI) in proposing the Cell and Gene Therapy (CGT) Access Model (Model) and highlight other areas that we urge CMS to consider.

In recent years, we have seen numerous lifesaving and life-enhancing CGTs for some of the most difficult-to-treat conditions, including cerebral adrenoleukodystrophy, Beta-thalassemia, spinal muscular atrophy, certain kinds of hemophilia, and numerous cancers. We are excited about the robust pipeline of these products, which includes the next generation of therapies that promise to provide durable treatments, and possibly cures, for diseases affecting vulnerable communities like sickle cell disease and hemophilia patients, including such patients enrolled in both Medicare and Medicaid.

We are closely monitoring CMMI's recently announced CGT Access Model. Under the Model, CMS would coordinate and administer multi-state, outcomes-based agreements (OBAs) with manufacturers of certain CGTs on behalf of participating states. According to CMMI, as new CGTs come to market, this will help Medicaid beneficiaries gain access to potentially life-changing drugs for illnesses like sickle cell disease and cancer. We believe the Model has the potential to enhance access to these transformative therapies among Medicaid beneficiaries given the current barriers in setting up OBAs because of limited state resources to implement these complex arrangements.

We commend CMS for recognizing the unique challenges facing Medicare and Medicaid with respect to C&GT access, coverage, and reimbursement. If designed properly, outcomes-based agreements and other value-based arrangements can improve access to the coming wave of cell and gene therapies for beneficiaries of state Medicaid programs. We urge CMMI to work closely with all stakeholders to develop more detailed specifications to ensure that the Model can meet its intent to ensure appropriate, equitable, and sustainable access to CGTs immediately upon their launch. To best enhance transparency and accountability, we urge CMS to include formal input processes for these stakeholders through a request for information (RFI) to solicit comments on model design, with additional opportunities for public comment once the model specifications are announced. In addition, to protect and promote equitable access, the Model should be piloted on a small scale, and each included OBA must be tailored to the relevant therapy in collaboration with the product's manufacturer, who has the deepest trove of clinical data and greatest familiarity with the product. Further, we support that the Model be voluntary for states and manufacturers as outlined in the announcement, and therefore the model design must not include undue inducements or pressure to participate.

While the Centers for Medicare & Medicaid Services (CMS) works with CMMI to implement the Model, we urge the agency to also consider the following issues that could further advance coverage and payment policies that comprehensively address barriers to providing meaningful and timely access to CGTs for both Medicaid and Medicare beneficiaries.

- Cross Border Credentialing Standard - First, we urge CMS to develop a minimum national credentialing standard for providers seeking to administer CGTs to out of state beneficiaries. Considering the specialized experience required for the administration of CGTs, manufacturers often contract with a limited number of specialized "Centers of Excellence," to provide the product, which tend to be located in a limited number of states. Federal regulations contemplate access to out-of-state providers for Medicaid beneficiaries; however, the provider is only authorized to bill for such services if the provider is credentialed by the patient's home state Medicaid program. Currently, each state establishes its own credentialing standards and requirements, which can be variable, onerous, complex, and time-consuming such that certain providers may be reluctant, or even unable, to complete process necessary for the treatment of nonresident beneficiaries. A universal minimum credentialing standard across all state Medicaid programs would streamline the credentialing process and facilitate the treatment of CGT patients by out-of-state providers, thereby avoiding unnecessary delays and other barriers to care for these patients.
- Medicaid Reimbursement for CGTs - Second, we urge CMS to encourage state Medicaid programs to adequately reimburse providers for the administration of CGTs, such as through the adoption of separate payment methodologies. Many CGTs are administered in the inpatient setting, under which states pay providers a bundled rate that is generally inadequate to cover the hospital's cost of purchasing these innovative new therapies. As a result, hospitals may face significant financial losses when administering CGTs to Medicaid beneficiaries, which can discourage utilization in this population. A limited number of states are beginning to pay hospitals separately (i.e., outside of the bundle) for their acquisition cost of CGTs. Since separate payment can make hospitals whole for the costs incurred for purchasing CGTs, CMS should issue guidance encouraging states to adopt this methodology to encourage the administration of these therapies by providers.
- Frequency of NTAP Determinations for CGTs – Finally, to expedite access to innovative new CGTs for Medicare patients delivered in the inpatient setting, we urge CMS to increase the frequency of the New Technology Add-on Program (NTAP) determinations. The current annual process provides for NTAPs only at the beginning of the fiscal year, and only for products approved by FDA no later than the previous July 1. This requirement unnecessarily delays access to innovative and often lifesaving therapies for Medicare beneficiaries, especially those approved just after the deadline. In this year's proposed Fiscal Year 2024 update to the inpatient prospective payment system (IPPS) rule, CMS proposes to move the cutoff date even earlier in the year in order to reduce the administrative burden on CMS. However, this would create even longer access delays. Rather we suggest that as CMS works to finalize the rule, the agency considers more frequent NTAP determinations for CGTs, similar to what CMS already does for certain infectious disease products, as an alternative means to reduce the administrative burden on the agency while also facilitating expanded access to innovative new CGTs.

We appreciate the Administration's focus on improving access to CGTs and look forward to working with you and other stakeholders to address the issues mentioned in this letter to improve and expedite access to these transformative therapies.

If you have any questions, please contact XXXXX

Sincerely,