American Society of Gene + Cell Therapy

June 24, 2020



The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore MD 21244

Regarding: Oklahoma Health Care Authority Healthy (OHCA) section 1115(a) demonstration waiver amendment request to incorporate the Health Adult Opportunity (HAO) initiative (Project Number: 11-W00048/6)

Dear Administrator Verma:

The American Society of Gene & Cell Therapy (ASGCT) is writing in response the to the OHCA request to amend its section 1115(a) demonstration project by incorporating conditions of the HAO initiative. ASGCT is a professional membership organization representing over 4,200 individuals, including scientists, physicians, and other professionals in gene and cell therapy working in settings such as academic institutions, hospitals, and biotechnology and pharmaceutical companies. Many of our members have spent their careers in this field performing the underlying research that has led to today's robust pipeline of transformative therapies.

A core portion of the Society's mission is to advance the discovery and clinical application of genetic and cellular therapies to alleviate human disease; therefore, the accessibility of such therapies to patients is of paramount importance to ASGCT. The Society is concerned that the OHCA's requested amendment to its Section 1115(a) demonstration project (SoonerCare 2.0) could restrict patient access to gene and cell therapies, which are at the forefront of medical innovation.

Two facets of the SoonerCare 2.0 proposed amendment are of particular concern to ASGCT. First, as the application notes on page 21, the state's proposal is "to introduce premiums… which prior experience has shown to depress enrollment." Additionally, the application includes options for sliding-scale premiums based on income and household size, as well as point-of-service co-pays. Enrollees failing to meet these new premium and cost-sharing requirements would be subject to termination. Such provisions could result in an increasing number of uninsured patients who would therefore lack access to gene therapies, which could transform lives.

SoonerCare 2.0 would also eliminate retroactive coverage for enrollees under the hypothesis that, per page 57 of the application, "SoonerCare 2.0 members will be more likely than other Medicaid members to enroll in



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coverage before they experience an acute health care need." This premise is unsupported, and could result in a lack of retroactive coverage for low-income Oklahomans. ASGCT views this combination of depressed enrollment, enrollment termination, and elimination of retroactive coverage as a potential significant risk to patient access to care, including to gene and cell therapies.

ASGCT is also concerned about the defined budget target identified in the SoonerCare 2.0 proposed amendment. Because the federal government would not match spending in excess of the state-identified target, such a spending cap would bias patient care away from high-value, disease-modifying, potentially single-administration gene therapies with accompanying higher upfront costs, but the potential to offer more positive health outcomes. As additional gene therapies receive FDA approval, more restricted state budgets under this initiative could result in lack of coverage for the one-time costs of these therapies, ultimately jeopardizing patient access to life-changing treatments.

Finally, as noted on page 27 of the SoonerCare 2.0 application, Oklahoma intends to provide prescription drug benefits in line with section 1927 of the Affordable Care Act at this time. However, the proposal includes the intention to explore "the potential benefits of a limited prescription drug formulary." Explicit in the prospect of a closed or limited formulary is a shift away from long-standing patient protection rules that require states to cover any FDA-approved drug. Such closed formularies could provide additional barriers to access for gene and cell therapies, such as CAR T-cell therapies, which are already restricted due to limited provider sites and reimbursement gaps across payers. Future access also could be problematic for additional gene therapies in the pipeline for diseases that have adult Medicaid populations, such as those for hemophilia and sickle cell disease.

ASGCT appreciates the thoughtful consideration CMS is giving to the payment ecosystem as science continues to produce innovative products that will revolutionize patient care. Ultimately, the Society's goal is to encourage patient access to these potentially curative treatments.

Please let us know if you have any questions for which we may provide assistance.

Sincerely,

David Barrett, JD
Chief Executive Officer
American Society of Gene & Cell Therapy