American Society of Hematology
Helping hematologists conquer blood diseases worldwide

2026
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February 19, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
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Submitted electronically via Regulations.gov

Re: Global Benchmark for Efficient Drug Pricing (GLOBE) Model, CMS-5545-P

Dear Administrator Oz,

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Global Benchmark for Efficient Drug Pricing (GLOBE) Model. We appreciate the opportunity for public review and submission of comments on the proposed model. Stakeholder feedback is vital to ensuring that proposed model supports the delivery of high-quality care without unintended consequences, while ensuring access to lifesaving drugs and biologics.

ASH represents more than 18,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions like sickle cell disease, thalassemia, and venous thromboembolism. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, transfusion medicine, and gene and cell therapies. Our mission is to foster high-quality care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders. With these goals in mind, we provide comments on the GLOBE model focusing on the potential exclusion of cell and gene therapies (CGTs) from the model.

The GLOBE Model is a proposed mandatory payment model developed by CMS under the Innovation Center. The model is designed to evaluate whether tying Medicare Part B drug payments and rebates to international price benchmarks may reduce Medicare spending and lower beneficiary out-of-pocket costs, while maintaining access to high-cost drugs.

Of note, ASH appreciates that the agency requested comments on excluding CGTs from the model. CGTs, per the rule text are cellular immunotherapies, cancer vaccines and other products aimed to treat or prevent certain diseases including cancer, genetic diseases, and infectious diseases. Cell and gene therapies are an important treatment option for the patients ASH members treat since these therapies directly target or even correct the underlying cause of disease rather than just managing symptoms. For many blood cancers and inherited blood disorders, these therapies offer the potential for long-lasting remission or cure, particularly for patients who have exhausted standard treatment options. CGTs may also be highly personalized, using a patient's own cells, which can improve effectiveness and reduce ongoing treatment burden.

Examples of serious hematologic diseases that may be treated with CGTs include the following.

- Leukemias, such as acute lymphoblastic leukemia (ALL), in which Chimeric Antigen Receptor (CAR) T-cell therapies target cancerous blood cells.
- Lymphomas, including diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma, treated with CAR T-cell and other cellular immunotherapies.
- Multiple myeloma, using CAR T-cell therapies that target plasma cells.
- Sickle cell disease, where gene therapies modify or correct the patient's own blood-forming stem cells so they produce non-sickling hemoglobin to greatly reduce or in some cases eliminate painful crises and other complications.
- Beta thalassemia, treated with gene therapies that restore functional hemoglobin production and reduce or eliminate the need for chronic transfusions.

ASH recommends that CGTs be excluded from the GLOBE model. The fundamental principle of the model, using international reference pricing to calculate manufacturer rebate amounts, is not applicable for these drugs and therapies and therefore an exclusion would be appropriate for the reasons stated below.

Lack of International Pricing Benchmarks

The international pricing data needed to support the GLOBE benchmarking methodology is problematic for CGTs. Many CGTs are not available outside the U.S., often due to the absence of viable reimbursement pathways in other countries.

In instances where international pricing does exist for CGTs, it is either difficult to access or may be unusable for benchmarking purposes. Our experts have found that most countries rely on confidential outcomes-based agreements for CGTs, meaning that publicly available list prices bear little or no relationship to the actual net price paid for the drug or therapy. The Innovation Center is already studying outcomes-based agreements for gene therapies for sickle cell disease in the Medicaid program as part of another model; this is discussed further below. As a result, reliance on public international prices may produce benchmark figures that do not reflect real-world transactions and would distort payment calculations under the GLOBE Model. Essentially, the data CMS would need to implement international reference pricing for CGTs in a meaningful way largely do not exist.

Clinical Concerns and the Problem of Inappropriate Comparisons

Of particular importance, many CGTs have no true biologically similar comparators, and yet we have heard that payers sometimes treat distinct therapies as interchangeable, leading to inappropriate coverage denials or pressure to substitute one product for another. For CGTs, clinical differences matter given the specialized process to create these therapies; we note that products within the same therapeutic category are not necessarily equivalent, which may lead to price comparisons and benchmarking that are not logical.

CMS Innovation Center Model Already Exists for CGTs

As mentioned above, CGTs are already the subject of active alternative payment model testing through the CMS Innovation Center's CGT Access Model. The Innovation Center notes that this model is the first of its kind, with the federal government negotiating outcomes-based agreements with CGT manufactures on behalf of state Medicaid agencies. The Society has been supportive of the CGT Access Model, and we believe that including CGTs within the mandatory GLOBE Model, at the same time as the testing period for the CGT Access Model, would create significant overlap and confusion. Running these two distinct payment models with differing types of payment structures will make it difficult for the Agency to evaluate whether either model is improving access to CGTs while keeping costs manageable.

Risks to Innovation and Reduced Access to CGTs

Applying international reference pricing to CGTs could weaken manufacturer incentives to develop new therapies, particularly for rare or complex conditions where there are very few therapies available. Cell and gene therapies rely on highly specialized and often patient-specific manufacturing processes with limited production capacity. Reimbursement policies that introduce significant or unpredictable payment changes, particularly for high-cost therapies like CGTs, can influence manufacturing decisions that may threaten supply stability and worsen existing supply-chain vulnerabilities.

ASH strongly recommends that CMS exclude CGTs from the GLOBE Model and instead explore alternative payment approaches that better reflect the unique and often lifesaving nature of these therapies.

If you have questions or need additional information, please contact Carina Smith, Manager of Health Care Access Policy (casmith@hematology.org).

Sincerely,

Robert Negrin, MD
President