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September 9, 2024

VIA ELECTRONIC DELIVERY

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1809-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: IGT Comments on FY 2025 OPPS Proposed Rule [CMS-1809-P]

Dear Administrator Brooks-LaSure:

The Institute for Gene Therapies (IGT or "the Institute") is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS or "the Agency") regarding the Calendar Year (CY) 2025 Hospital Outpatient Prospective Payment Systems (OPPS) Proposed Rule ("the Proposed Rule").[1] The Institute launched in February 2020 as a multi-stakeholder coalition that advocates for a modernized regulatory and reimbursement framework to promote the development of transformative gene therapies and enhance patient access. IGT is dedicated to promoting the value of transformative gene therapies and advocating for policies and practices to ensure that patients that require these treatments can access them. Our most vulnerable patients and their families anxiously wait to access these gene therapies and the life-altering benefits they offer for the treatment of some of the most debilitating or rare diseases. The Institute represents a wide array of patient advocacy groups, gene therapy manufacturers, and scientific, medical, and academic stakeholders seeking to advance the promise of gene therapies, through the collaboration of the Corporate Advisory Council, Patient Advocacy Advisory Council, and Scientific, Academic & Medical Council. A full list of our members is available at https://www.gene-therapies.org/_files/ugd/b11210_c2ec04ef7d9c496887611cfb16f24388.pdf?index=true.

Adequate payment in Medicare is essential to ensuring access to gene therapies and reducing disparities among patients who receive treatment. Gene therapies have the potential to transform how we treat diseases in this country, particularly serious conditions with high unmet medical need. We are seeing that potential come to fruition today, with gene therapies approved and administered for patients with conditions like sickle cell disease and spinal muscular atrophy, among others. When access to these treatments is improved across the population, we have the tools to help prevent significant health inequities. IGT commends CMS' efforts to facilitate policies that improve increased access to critical therapies, particularly gene therapies. To that effect, IGT provides comments in response to the proposal included in *Section II.A.2.b(4) Exclusion of Cell and Gene Therapies from Comprehensive Ambulatory Payment Classification (C-APC) Packaging.*

[1] 89 Fed. Reg. 59,186 (July 22, 2024).

I. Exclusion of Cell and Gene Therapies from Comprehensive Ambulatory Payment Classification (C-APC) Packaging

For CY 2025, CMS proposes to exclude payments for select cell and gene therapies from payment for the primary C-APC service when the identified therapies appear on the same claim as primary C-APC services. This proposal would be effective for one year. The Agency asserts that the cell and gene therapies listed in the proposal are primary and independent therapies that do not necessarily assist in the delivery of the primary procedures assigned to a C-APC; therefore, CMS proposes that these should be excluded from C-APC packaging. CMS lists nine cell and gene therapies for which this proposed exclusion policy would apply, Yescarta, Kymriah, Provenge, Tecartus, Breyanzi, Abecma, Carvytki, Luxturna, and Zolgensma.

As stated by CMS, the Agency treats items and services on the C-APC claim as "as integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a comprehensive service." IGT agrees with CMS that the gene therapies listed are primary treatments and should be treated as such. IGT supports that under no circumstance is it appropriate to package a primary treatment into the C-APC packaging, and the listed therapies do represent primary treatments. However, CMS is only proposing this exclusion for CY 2025 to gather additional information on this policy. **IGT commends the Agency and fully supports its proposal** not to package payment for the listed nine cell and gene therapies into payment for the primary C-APC service when they appear on the same claim, and **IGT urges the Agency to extend this past CY 2025 and implement this proposal permanently.**

Further, CMS is soliciting information regarding other classes of drugs, biologicals, or other products that are clearly not considered "integral, ancillary, adjunctive, or supportive of a primary C-APC service but could appear on the same claim as the C-APC for that primary service and for which payment would be packaged into the C-APC payment under our current policy." **IGT recommends CMS categorically exclude gene therapies from the packaging of payment for the primary C-APC service when gene therapies appear on the same claim as primary C-APC services**. Additionally, IGT recommends CMS automatically exclude cell and gene therapies for which pass-through is expiring from the C-APC packaging policy. It is important to note that while IGT does support the proposal to exclude certain gene therapies from C-APC packaging, IGT believes CMS should bolster this policy with adequate payment in the outpatient setting, particularly given the number of gene therapies that will target conditions prevalent in populations who have and continue to experience severe health inequities. Many gene therapies in development have the potential to reverse decades of health inequities faced by disadvantaged populations and Medicare's coverage and reimbursement policies will directly determine whether these populations have access to life-changing medical breakthroughs.

II. Conclusion

IGT appreciates the Agency's efforts to improve gene therapy payment under the Medicare OPPS, and these efforts will have significant implications for patient access. IGT welcomes every opportunity to engage with CMS over the coming years regarding broader payment concepts to ensure a strong future for gene therapy across payer systems. We would be pleased to serve as a resource on gene therapy issues and answer any questions regarding these comments.

Sincerely,

John R. Feore, III
Director, Health Policy and Advocacy
Institute for Gene Therapies