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Challenges to Reimbursement for Cell and Gene Therapies for Payers Like Medicare

Submitted by Arnold & Porter

Cell and gene therapies (CGTs) represent tremendous scientific advancements for serious conditions and have upended how many diseases are treated and, in some cases, cured. Often indicated for small patient populations, CGTs can be incredibly expensive, costing hundreds of thousands of dollars for a single treatment, and resource intensive. Accordingly, by their very nature, CGTs present unique reimbursement challenges, particularly for payers like Medicare.

Significantly, the Centers for Medicare & Medicaid Services (CMS) lacks the flexibility of other payers in that it is constrained by the Medicare statute, which structures the program based on benefit categories, settings of care, and associated payment systems, making it difficult for Medicare to keep pace with improvements in medical care and innovative therapies such as CGT. Recent treatments, such as chimeric antigen receptor (CAR) T cells, serve as an instructive example of how payers like Medicare have approached reimbursement, and in some cases, adapted its policies to address CGTs while working within the confines of its authorities.

To date, the hospital has been the primary setting where gene therapies such as CAR T have been provided under Medicare. The applicable setting (inpatient vs. outpatient) is often driven by factors such as the severity of potential adverse events and required length of observation stay, which in turn, impact Medicare payment. Similarly, depending on the payment methodology, the type of administration procedure can affect whether Medicare pays separately or packages the payment into a procedure. Initial CGTs required inpatient monitoring, making the inpatient hospital setting the operative payment system for CMS to first tackle reimbursement.

Generally, the Medicare hospital inpatient payment system is not well designed to reflect high cost, low volume technologies, because Medicare makes one comprehensive, prospectively determined payment per stay (inclusive of therapies and drugs) based on a patient's diagnosis and assignment to a Diagnosis Related Group (DRG). The system is not intended to cover any given hospital's costs; rather, it is designed to

incentivize hospitals to operate efficiently in furnishing quality care and minimize unnecessary costs. This presents challenges for new therapies like CGTs—existing DRGs are based on existing therapies and thus may not be reflective of new high cost items. Indeed, the initial DRG assignment for CAR T therapy had a payment amount far lower than the high price tag for the treatment. After collecting sufficient cost data, CMS eventually established a new Medicare Severity-DRG (MS-DRG 018) specific to CAR T and "other immunotherapies" (*i.e.*, to capture other cell therapies under CMS' pre-major diagnostic category grouping logic) and significantly, used a different methodology to develop the relative weight in a way that was significantly higher than usual, ensuring greater reimbursement.

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Medicare's inpatient hospital system does build in other adjustments for added payment, as applicable, including outlier payments to help cover extremely costly cases and new technology add-on payments, the latter of which is based on the satisfaction of certain criteria regarding newness, cost, and substantial clinical improvement. Even when available, however, such adjustments may not make hospitals whole and for new technology add-on payments, are temporary.

As more high-cost CGT innovations come to market and potentially apply to larger patient populations and shift to other sites of care like outpatient hospital settings, payers like Medicare will continue to navigate reimbursement. Changes in reimbursement are likely to lag behind therapeutic innovations, and CGT companies may want to better understand current payment systems to identify ways to prepare those systems to accommodate new technologies. ■