Medicaid Best Price and Its Implications on Cell and Gene Therapy Products

While cell and gene treatments could provide cures, their high potential value may often come with a high price tag. These therapies can cost hundreds of thousands of dollars, if not millions. Given limited resources, payers are looking for some certainty these treatments are going to work.[1] One solution would be an outcomes-based agreement, except stakeholders have been concerned that these arrangements could run afoul of best price regulations and/or anti-kickback statutes In this issue brief, we highlight the regulatory changes that the Centers for Medicare & Medicaid Services (CMS) finalized in late 2020 to modernize Medicaid prescription drug purchasing and to propel payment innovation by providing states, private payers, and pharmaceutical manufacturers with additional flexibility and choice when entering value-based purchasing (VBP) agreements.[2]

Cellular Therapy

Cellular therapy refers to the replacement or repair of damaged tissues and/or cells with human cells, using living cells instead of drugs. With the advent of new technologies, innovative products, and limitless imagination, it is now possible to use a variety of different types of cells as a therapy or treatment for a variety of diseases and conditions.[3]

Gene Therapy

Gene therapy replaces a faulty gene or adds a new gene in an attempt to cure disease or improve a body's ability to fight disease. Gene therapy holds promise for treating a wide range of diseases, such as cancer, cystic fibrosis, heart disease, diabetes, hemophilia, and AIDS.[4]

Background

The Medicaid best price (MBP) policy requires that a drug manufacturer offer state Medicaid programs the best price they offer to any other purchaser (with a few exceptions) or a discount of 23.1% off the list price (whichever is lower). In turn, Medicaid programs are required to cover all the manufacturer's prescription drugs, with a few exceptions. Stakeholders are concerned that MBP requirements have limited the range of payment arrangements manufacturers and payers can pursue.[2]

Cell and gene therapy (CGT) manufacturers have indicated MBP limits their willingness to enter VBP agreements. If they provide a payer a partial or full refund for a failed therapy, Medicaid programs could determine that is the new best price for any enrollee who undergoes that therapy. As a result, manufacturers could conceivably have to offer their CGT for free to all Medicaid enrollees.

Best Price Reforms

The final rule from CMS titled "Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482-F)," released on December 21, 2020, seeks to make it easier for state Medicaid programs, commercial insurers, and pharmaceutical manufacturers to enter into VBP arrangements tied to clinical outcomes for prescription drugs. The regulation originally scheduled the requirement to take effect on January 1, 2022; however, the Biden administration has delayed its implementation until July 1, 2022.[5]

The rule aims to reduce the impact on MBP when a manufacturer must offer a rebate, discount, or partial/full refund due to terms of the VBP agreement. **The new rule will provide manufacturers with 2 options for reporting prices paid by eligible, usually commercial, customers under VBP arrangements:**

Bundled sales: Manufacturers average the price paid under a customer contract. This option minimizes the impact of a partial success by averaging its price with the prices of the fully successful therapies.

Multiple best prices: Manufacturers can establish separate best prices for each of multiple performance tiers. For example, manufacturers could establish one best price for a partially successful therapy and a different, higher best price for a fully successful therapy. Medicaid would then apply the appropriate best price to its enrollees, depending upon the success of their therapy.

Impact on Cell and Gene Therapies

The revisions to MBP may be one avenue to increase patient access to cell and gene therapies, as payers or other risk-bearing entities may be more likely to cover these medications if their use may result in significant health benefits for patients or a significant reduction of overall healthcare costs. Access to CGTs is a complex and multi-faceted matter, but VBP arrangements could begin providing payers with assurances regarding the effectiveness of high-cost medications and allow payers to consider removing prior authorization requirements or other forms of utilization management for high-cost medicines, thus increasing patient access and alleviating provider burden.

CMS may, as a result of its final rule, be looking for ideas to improve Medicare Part B based on the VBP arrangements that successfully emerge in private plans and Medicaid. Such learnings may be explored by the CMS Innovation Center via demonstrations.

References:

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