Perspectives on State and Federal Medicaid Policies

Medicaid Landscape: Medicaid Approaches to Cell and Gene Therapy Coverage and Reimbursement

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Medicaid Coverage & Reimbursement: Overview

- State Medicaid program coverage and payment for cell and gene therapies vary from state-to-state. Key factors include:
  - Fee-for-service vs. managed care organization
  - Category of coverage (inpatient hospital service vs. drug)
  - Setting of service (inpatient vs. outpatient setting)
  - A state’s own coverage and medical necessity policies
  - A state’s own payment policies
Medicaid Coverage of Transformative Therapies

- Historically, state Medicaid programs have sought to include the cost of drugs and other transformative therapies in the bundled payments made to hospitals, meaning that hospitals are not separately reimbursed for drugs they provide to their patients.

- However, several states have recently experimented with payment systems that do attempt to recognize the new transformative therapies.
Review of CAR-T-specific Medicaid payment policies for most populated states in the U.S.
- Each state Medicaid program presents different complexities and methodologies

Most state Medicaid programs reimburse hospitals for CAR-T treatments pursuant to a **bundled/episodic payment methodology**
- State Medicaid programs generally reimburse hospitals on a bundled/episodic basis termed the All Patients Refined Diagnosis Related Groups (APR DRG)
- The APR DRGs are generally modeled after the Medicare MS-DRGs but account for a broader range of patient characteristics (e.g., non-Medicare individuals)
Limited Medicaid programs have “carved out” payment for CAR-T from the bundled payment when administered in the inpatient setting

- **Examples**: Massachusetts, New York, California, Indiana, Washington

Most state Medicaid programs **do not** explicitly address payment for CAR-T under FFS/ Medicaid managed care
Indicates state has in place a FFS CAR-T reimbursement policy
MassHealth was the first state Medicaid program to announce a specific payment policy for cell and gene therapies based on access concerns from academic medical centers.

- Effective March 1, 2018 MassHealth revised its Hospital Reimbursement Contract to carve out certain cell and gene therapies from the inpatient and outpatient bundle to be paid separately.

Hospital reimbursed at lowest of: invoice cost, WAC, or Medicare Part B rate.

- Invoice cost is net of all on or off invoice reductions, discounts, rebates, charge backs or similar adjustments received by hospital.

Hospitals must make “every effort” to enter into “efficacy-, outcome-, or performance-based guarantee (or similar arrangement)” related to the drug.

To date carve-out list includes Kymriah and Yescarta.

- Hospital required to enter into the performance based contract offered for Kymriah.
NY Medicaid Carve-Out Policy

- **New York** quickly followed MassHealth to reimburse hospitals for carved-out CAR-T therapies based on **actual acquisition cost for both inpatient and outpatient administrations**
  - Stated purpose is to ensure access to new therapies
  - State will only reimburse hospital’s actual costs, and will not reimburse hospital where performance guarantee has not been met (assuming VBA)
- All rebates paid to hospital for failed performance guarantees must be paid to state
- Carved out therapies include **Kymriah, Yescarta** and **Luxturna**
- Applies to **Fee for Service only**
Other examples of CAR-T separate payment policies

- CMS approved a SPA for California on June 21, 2019 for CAR-T carve-out when administered in the inpatient setting, limited to FY 2019/20 (no managed care provision)
- Indiana adopted a policy in August 2019 carving out CAR-T from inpatient DRG for both FFS and managed care
  - Therapies paid pursuant to outpatient fee schedule
- Washington reimburses Kymriah and Yescarta separately at AAC in FFS; therapies are carved out of managed care and reimbursed FFS
If a cell or gene therapy meets the definition of a “covered outpatient drug” the Medicaid drug rebate program may apply:

- Under Section 1927 of the Social Security Act, a manufacturer typically must enter into an agreement under which a manufacturer agrees to pay rebates to states in exchange for the state guaranteeing coverage of the manufacturer’s “covered outpatient drugs.”
  - Note: Does not include drugs bundled into hospital services.
- In exchange for the manufacturer entering into a rebate agreement, a state “may exclude or otherwise restrict coverage” of a covered outpatient drug under only limited circumstances.
- Rebate amounts include a base rebate (23.1% of AMP), an inflationary penalty, and any optional supplemental rebates
Thank you!

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