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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

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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**

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Research: Landscape Review of Medicaid Coverage

- 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)

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Research: Landscape Review of Medicaid Coverage

- **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

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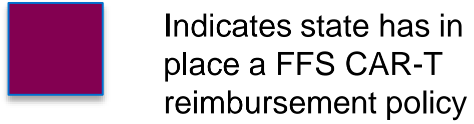
Survey of FFS Reimbursement Policies



Hawaii

Alaska

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MassHealth Carve-Out 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

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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

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Other State-Specific Carve-Outs

- **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

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Medicaid Coverage & Reimbursement: Outpatient Drugs

- **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

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Thank you!

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