Variation in Medicaid and Commercial Coverage of Cell and Gene Therapies

Beinfeld MT, Rucker JR, Jenkins NB, de Breed LA, Chambers JD

Center for the Evaluation of Value and Risk in Health, Tufts Medical Center, Boston, MA

August LLC, New York, NY

Poster Code: HPR19

BACKGROUND & OBJECTIVE

- Cell and gene therapies (CGTs) promise potentially transformative treatments for a growing array of diseases, but they pose a challenge to payers due to their one-time administration, high costs and uncertain long-term benefits.
- Medicaid and Commercial plans pay a disproportionate share of reimbursement for CGTs. In this study we examined variation in access to CGTs both within and across Commercial and Medicaid plans.

METHODS

Data Source

- We created a database of coverage policies for 11 CGTs issued by 18 of the largest commercial health plans and Medicaid fee-for-service programs (50 states and DC) in 2021.
- We used the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database for commercial health plans and searched individual state websites for Medicaid program information.

Analyses

- We categorized coverage criteria as follows:
  - ✓ *Patient subgroup restrictions* (requirement for patients to meet particular clinical criteria, e.g., symptoms of particular severity or duration),
  - ✓ *Step therapy protocols* (requirement for patients to first try and fail an alternative drug or treatment),
  - ✓ *Prescriber requirements* (requirement for a certain type of physician to prescribe a drug), and
  - ✓ *Any other type of restriction* (requiring a drug to be used in combination with another treatment.
- We compared coverage restrictions both between and across Commercial and Medicaid plans.

RESULTS

- We identified 167 Medicaid and 198 Commercial coverage policies for the 11 CGTs.
- 68% of Medicaid and 54% of Commercial policies included coverage restrictions beyond the FDA labeled indication.
- Restrictions were more likely for certain CGTs than others. Policies for Zolgensma for spinal muscular atrophy and Luxturna for retinal dystrophy were most likely to include restrictions. Policies for Imlygic for melanoma and Yescarta for follicular carcinoma were least likely to include restrictions.
- Clinical coverage restrictions were common for all CGTs. Clinical restrictions most likely involved patient frailty or function, disease severity, and/or patient age.
- Health plans varied in use and type of clinical restrictions and cutoffs for patient frailty, gene requirements, and age.
- Step therapy protocols were rare.
- Prescriber requirements were common.

Figure 1. Restrictions on Access to 11 Cell and Gene Therapies Relative to FDA Label, Medicaid vs Commercial Health Plans, 2021

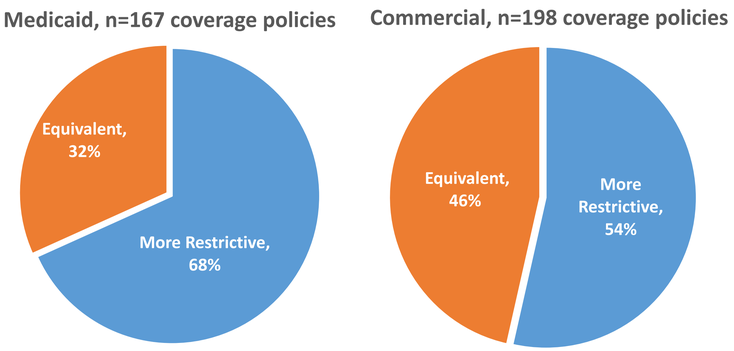
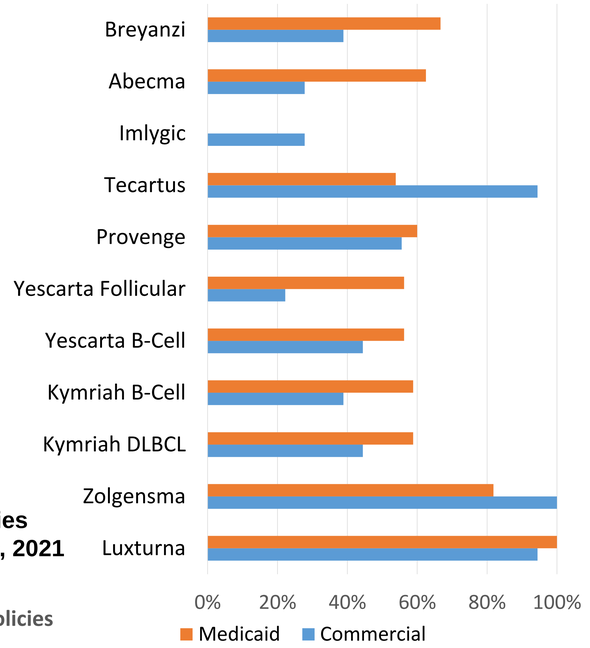


Figure 2. Proportion of Cell and Gene Therapy Policies With at Least one Coverage Restriction, Medicaid vs Commercial, 2021



- Medicaid plans were more restrictive than Commercial plans for 8 out of the 11 CGTs.
- The largest discrepancy in restrictiveness between Medicaid and Commercial plans was for Yescarta for follicular carcinoma, Abecma for multiple myeloma and Breyanzi for large B-cell lymphoma.

CONCLUSION

- In 2021 Medicaid plans were more likely to include restrictions on access to 11 CGTs than Commercial plans.
- We observed variation in clinical requirements both across and within Medicaid and Commercial plans.
- Variation between health plans may be due to differing budgets, patient populations, and contracts.
- Our research suggests that access to CGTs is more restrictive than other specialty drugs, owing to their high costs and complex administration.
- Variation in health plan behavior and coverage policy complexity has important consequences for patients and prescribing physicians.
- Novel payment mechanisms for CGTs promise a balance of access and affordability, while generating new evidence.

REFERENCES

1. Chambers JD, et al. Specialty Drug Coverage Varies Across Commercial Health Plans In The US. *Health Aff (Millwood)*. 2018 Jul;37(7):1041-1047.
2. Tunis S, Hanna E, Neumann PJ et al. Variation in market access decisions for cell and gene therapies across the United States, Canada, and Europe, Health Policy 2021; 125(12): 1550-1556

FUNDING

This was an unfunded research project.

CONTACT

For more information on the SPEC database, contact James Chambers at james.chambers@tuftsmedicine.org.