Variation in Casgevy® and Lyfgenia™ Coverage Criteria Across State Medicaid Plans

Brennan CB[1], Rucker JA[1], Chambers JD[1]

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

BACKGROUND & OBJECTIVE

- In January 2025, the Centers for Medicare & Medicaid Services (CMS) launched the Cell and Gene Therapy (CGT) Access Model, a voluntary program to test whether centralized purchasing and coverage of high-cost cell and gene therapies can standardize Medicaid access[1].
- The model focuses on sickle cell disease therapies, exagamglogene automcel (Casgevy®) and lovotibeglogene automcel (Lyfgenia™).
- This study evaluates how state Medicaid plans, not participating in the model, cover these therapies and the extent of variation across states.

METHODS

Data Source

- We identified states participating in the CGT Access Model using program information from CMS. For nonparticipating states, we searched state Medicaid websites for coverage policies for Casgevy® and Lyfgenia™. All included policies were current as of December 2025.

Analyses

- We analyzed coverage criteria and categorized requirements that exceeded FDA-approved indications into the following categories:

1. ***Age restriction:*** Patient must be below a specified age (e.g., < 50 years).
2. ***Subgroup requirement:*** Patient must meet a specified vaso-occlusive event threshold.
3. ***Step therapy requirement:*** Patient must fail an alternative therapy before initiating the prescribed medication.

RESULTS

- Nine policies had imposed requirements exceeding the FDA-approved indication (Figure 1).
  - All 9 policies (100%) included patient subgroup restrictions with varying vaso-occlusive crisis (VOC) thresholds (Figure 2):
    - 6 (66.7%) required ≥2 VOCs over 2 years;
    - 1 (11.1%) required ≥2 VOCs over 1 year; and
    - 2 (22.2%) required ≥4 VOCs over 2 years
- Seven policies (77.8%) imposed step therapy requirements (Figure 2):
  - All seven policies (100%) required a patient to step through hydroxyurea therapy.
  - One plan additionally preferred Casgevy® over Lyfgenia™.
- Two (22.2%) policies imposed an age restriction, excluding patients older than 50 years old (Figure 2).

Figure 1. Medicaid state-level variation in model participation, December 2025

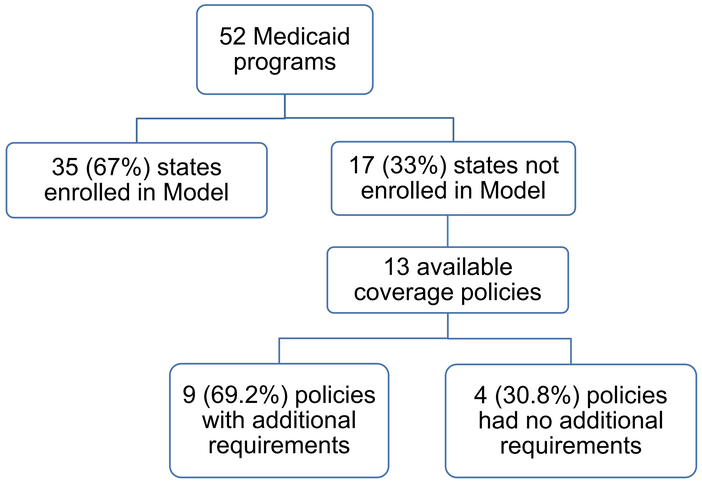
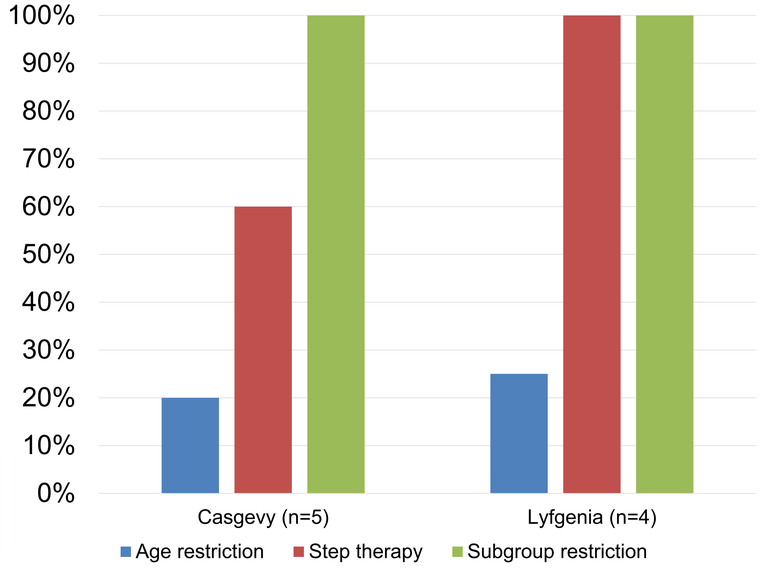


Figure 2. Prevalence of Coverage Criteria in Casgevy® and Lyfgenia™ Policies (n=9)

Proportion of Policies with Subgroup Restrictions n= 9 (100%)			Proportion of Policies with Age Restrictions n= 2 (22%)	Proportion of Policies with Step Therapy n= 7 (78%)
≥ 2 VOCs over 2 years	≥2 VOCs over 1 year	≥4 VOCs over 2 years	Excluding patients ≥ 50 years old	Failure of hydroxyurea
6 (66.7%)	1 (11.1%)	2 (22.2%)	2 (100%)	7 (100%)

Figure 3. Prevalence of Coverage Criteria in Casgevy® and Lyfgenia™ Policies



CONCLUSION

- Access to Casgevy® and Lyfgenia™ varies across states not participating in the CGT Access Model.
- In the absence of centralized decision-making, state Medicaid programs apply inconsistent coverage policies, leading to variation in access barriers for the same therapies.
- Greater standardization of coverage criteria may reduce geographic disparities for patients with sickle cell disease.

REFERENCES

1. Centers for Medicare & Medicaid Services. Cell and Gene Therapy (CGT) Access Model. Accessed March 25, 2026. https://www.cms.gov/priorities/innovation/innovation-models/cg

FUNDING

This research had no outside funding.

CONTACT

For more information about the SPEC Database, please contact James Chambers (james.chambers@tuftsmedicine.org).

Poster Code: HPR70