

## Rare Disease Coverage Trends

# Medicaid's Cell & Gene Therapy Access Model is up and impacting coverage

**As full-fledged implementation begins, the CMS program is set to benefit sickle cell patients covered in many states and reduce administrative burden for states and providers.**

CMS has negotiated multi-state outcomes-based agreements (OBAs) with the makers of the two FDA-approved sickle cell gene therapies – Casgevy (Vertex) and Lyfgenia (Genetix Biotherapeutics). As of the July-August 2025 rollout, 33 states, D.C. and Puerto Rico had opted in, covering roughly 84-85% of Medicaid beneficiaries with sickle cell disease.

States are taking different operational approaches – some moving CGT reimbursement to fee-for-service, others carving these products out of capitation – but the shared goal is the same: to test whether a CMS-led, pooled OBA model can expand access to breakthrough cell and gene therapies while stabilizing Medicaid budgets and ensuring manufacturers remain accountable for outcomes.

Stay ahead of shifting coverage trends across rare diseases like sickle cell with Clarivate's DRG Fingertip foundations [here](#).

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## Strategic Implications

There has been an increase in unbundling of Casgevy and Lyfgenia from medical benefits in Medicaid, leading to increased listing on formularies or other high-cost carve-out drug lists and greater clarity in coverage.

# DRG Fingertip data shows a substantial discrepancy between Commercial and Medicaid coverage rates for sickle cell:

Casgevy  
Lyfgenia

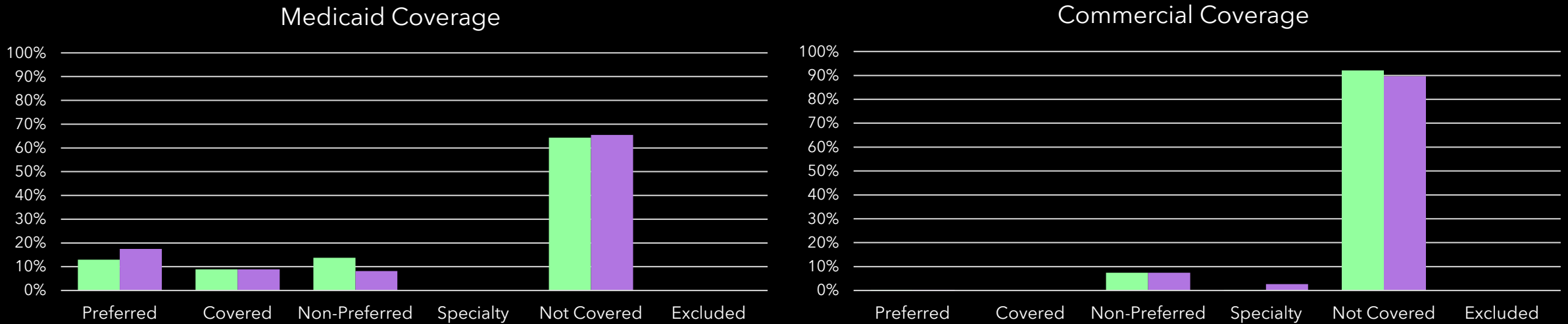


Figure 1. Coverage for sickle cell treatments by percentage of patient lives

## Key Takeaways

### Faster and broader Medicaid acceptance of gene therapies

Because CMS negotiated one multi-state outcomes-based agreement (OBA) on behalf of states, Medicaid agencies no longer need to negotiate individually with manufacturers – dramatically speeding up adoption.

### Reduced cross-border and administrative complexity

With 33 states, D.C., and Puerto Rico opting in, patients face fewer coverage gaps when moving, and states can avoid building their own complex OBA infrastructure.

### CMS centralizes data, outcomes tracking, and financial reconciliation

CMS, not individual states, sets clinical outcome measures, validates results, and calculates rebates for underperformance, simplifying analytics and reporting.

### More predictable planning for treatment-center capacity

Centralizing access allows states and manufacturers to jointly plan qualified treatment-center capacity, balancing site availability with expected patient volume – important for therapies that require specialized administration.