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RESEARCH BRIEF

By MIT NEWDIGS FoCUS Project

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Tracking Medicaid Coverage of Durable Cell and Gene Therapies

Durable cell and gene therapies represent a unique challenge to the US healthcare insurer/payer landscape, given the one-time treatment and associated high upfront cost but potentially durable outcomes. This study focuses on Medicaid coverage policies by state for Luxturna (for inherited form of blindness), Kymriah (for pediatric blood cancer acute lymphatic leukemia (ALL) and adult blood cancer diffuse large B-cell lymphoma (DLBCL)) and Yescarta (for DLBCL), which were all approved and launched in 2017.

Medicaid presents the most resource-constrained US payer type. While Medicaid is statutorily required to provide coverage to all FDA-approved products of drug manufacturers that participate in the Medicaid Drug Rebate Program (MDRP), the program is not centrally administered and coverage policies are determined by each state individually.[1] Studying these state coverage policies provides a spectrum of clarity and ease of patient access at the individual state level.

Coverage policies were sourced from public state documents (typically Prior Authorization forms, Preferred Drug List, Drug Utilization Review meeting minutes), as well as from direct communication with state health services officials (typically Pharmacy Services) from January to April 2019. Not all states were able to provide information.

KEY TAKEAWAYS

Explicit durable cell and gene therapy coverage in Medicaid programs varies across states, including prior authorization and associated criteria.

Not all states have issued coverage policies for Luxturna, Kymriah and Yescarta. The four largest states have coverage policies in place for all three products.

Prior authorization criteria associated with explicit coverage policies are typically based on the inclusion criteria of the clinical trials underlying the registration (and hence appear evidence-based) and contain step-therapy requirements, and thereby provide narrower coverage than the FDA label allows. The criteria. An initial review by clinical experts deemed these not to be overly restrictive.

Six states had no issued coverage policy for any of the therapies: Alaska, Arizona, Idaho, Kentucky, Nebraska and Virginia. Medicaid programs in Pennsylvania, New Mexico and North Carolina did not have issued coverage policies for Yescarta, while Massachusetts and Pennsylvania had no issued coverage policy for Luxturna.

The issuance of a coverage policy in a state can depend on whether these products are managed through the pharmacy or medical benefit, whether Medicaid is secondary payer, and the degree of managed care for Medicaid. States with the largest Medicaid/CHIP population (notably California, Texas, Florida

WHAT DID WE LEARN?

In states with available information (Table 1), most had explicit coverage policies for all three products (range: 69–74%). In states with confirmed coverage, the majority required pre-authorization. While variable, the criteria were within the FDA label and clinical trial inclusion

	Luxturna (n=34)	Kymriah (n=37)	Yescarta (n=35)
Coverage policy	25 (74%)	29 (78%)	24 (69%)
Requiring PA	16 (64%)	18 (62%)	16 (67%)
Not requiring PA	4 (16%)	7 (24%)	4 (17%)
Unconfirmed	5 (20%)	4 (14%)	4 (17%)
No (issued) coverage policy	9 (26%)	8 (16%)	11 (31%)

Table 1. Summary of national Medicaid coverage for Luxturna, Kymriah and Yescarta as of April 2019

and New York) had a coverage policy for all three products (See Figure 1). Most Medicaid patients have access to these recently launched durable therapies, but with some coverage restrictions. These results are consistent with a recent payer survey completed by the FoCUS project.[2]

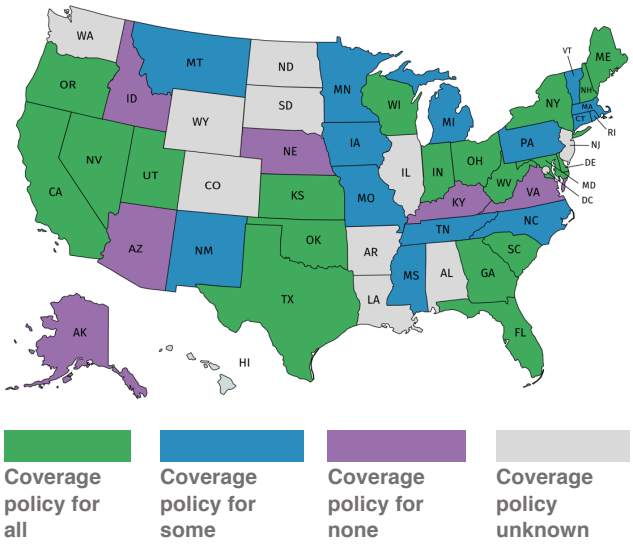

Figure 1. US Map illustrating state-by-state coverage of Yescarta, Kymriah, and Luxturna

REFERENCES

1. US Social Security Administration. Payment for Covered Outpatient Drugs. 1991. https://www.ssa.gov/OP_Home/ssact/title19/1927.htm#ft218. Accessed July 5, 2019.

2. MIT NEWDIGS FoCUS Project. Research brief 2019F206-v039-payer perspectives survey. http://newdigs.mit.edu/sites/default/files/FoCUS%20Research%20Brief_2019F206v039.pdf. Published June 26, 2019. Accessed July 5, 2019.

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ABOUT FOCUS

The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable and potentially curable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by these therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement in this endeavor.

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