

# **Gov. Pritzker Signs Executive Order To Promote Equity In Gene And Cell Therapy Treatment Access And Affordability**

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CHICAGO — Today, Governor JB Pritzker signed an Executive Order to create a framework for financing and expanding access to new and transformative therapies and

drugs, like the recently approved gene therapies for Sickle Cell Disease. New financing arrangements are necessary to ensure equitable access to novel and transformative therapies and drugs, and ultimately improve health outcomes for Illinois residents.

The executive order tasks the Illinois Department of Healthcare and Family Services (HFS) with leading the state's effort to establish payment models and financial structures that support access to new sickle cell disease treatments and other new high-cost drugs and treatment within the Illinois Medicaid program, and creates the Advisory Council on Financing and Access to Sickle Cell Disease Treatment and Other High-Cost Drugs and Treatment to provide HFS with input as the Department develops innovative and sustainable financing models. The Council will deliver a set of recommendations by Dec. 31, 2024.

"Historically we've seen breakthrough treatments end up out of reach for everyday Americans — strictly because of their cost," said Governor JB Pritzker. "My goal is to make emerging and transformative gene and cell therapy treatments affordable and available to all Illinoisans who need them. If we can narrow the affordability gap, those who are suffering from these diseases won't have to wait a generation before they can access these groundbreaking cures."

"Just like technologies and medicines advance, so too must our insurance systems," said Lt. Governor Juliana Stratton. "Removing obstacles allows doctors to provide more accurate, efficient treatment plans. Patients should not be forced through less effective treatments in an effort to save their insurer a few bucks - they should be focused on healing."

"HFS is committed to finding and implementing new and innovative ways to expand health care access for Medicaid customers in Illinois, and the Governor's action today will provide an opportunity to increase equitable access to sickle cell treatments and other high-cost drugs and treatment," said HFS Director Elizabeth Whitehorn. "Sickle cell disease in particular disproportionately affects people of color, and the high cost of this treatment creates a barrier that will be insurmountable for far too many. This executive order will help us to increase access, and significantly improve health outcomes and the quality of life for people across Illinois."

Sickle cell disease is a group of lifelong, inherited blood disorders that affect more than 5,000 Illinois residents. Sickle cell disease disproportionately affects people of color, particularly Black Americans. Sickle cell disease affects an estimated one in every 365 Black Americans and one in every 16,300 Latino Americans.

More than 40% of the Illinois residents who have been diagnosed with sickle cell disease are enrolled in Medicaid for their health insurance coverage, and nearly half of Illinois Medicaid customers with sickle cell disease have a severe form of the disease.

Despite the cause of sickle cell disease being known for nearly 70 years, racial discrimination within the health care system has meant a historic lack of resources has been dedicated to supporting research and treatment. As a result, a limited number of health care providers have expertise in comprehensively managing sickle cell disease, and individuals living with the disease often encounter geographic and cost barriers to accessing care, further exacerbating the existing inequities in the health care system that disproportionately affect people of color.

Sickle cell disease symptoms can appear in children as early as 5 months of age, and those diagnosed with sickle cell disease have a life expectancy that's over 20 years shorter than the general population. Individuals with sickle cell disease are also at higher risk for asthma, chronic pain and fatigue, depression, acute chest syndrome, stroke, and organ damage and failure.

The cost of managing sickle cell disease over a person's lifetime is immense, with an estimated lifetime cost of \$1.26 million to \$2.1 million in health care expenses overall, of which patients on average contribute between \$34,000 to \$53,000 in out-of-pocket expenses.

Under the leadership of HFS, the new Advisory Council will complete a comprehensive review of innovative approaches establishing sustainable payment models and financing structures for high-cost drugs and treatments, with a strong focus on value- and outcome-based models. The Advisory Council will then make recommendations to HFS on payment and financing options that could be adopted in Illinois.

“As one of the largest sickle cell programs in Illinois, we know the cost of managing pediatric sickle cell disease is substantial and can be overwhelming for a family with limited resources,” said Kelly Guglielmi, interim CEO, La Rabida Children's Hospital. “Today marks a remarkable step forward in ensuring all patients have access to high-quality care.”

“I'm excited on behalf of our patient population – our patients deserve cutting edge therapies,” said James LaBelle, MD, PhD, Director of the Pediatric Stem Cell and Cellular Therapy program at UChicago Medicine and Comer Children's Hospital. “The results of gene therapies are very promising and carry the hope of being definitive and

long-lasting, unlike a drug someone might have to take daily for the rest of their life. And since these treatments are based on a patient's own stem cells, every patient with sickle cell disease has a readily available stem cell donor: themselves."

The U.S. Food and Drug Administration (FDA) in December approved two milestone gene therapy treatments for the treatment and potential cure of sickle cell disease, as well as several other new cell and gene therapies.

Illinois also submitted a letter of intent to participate in a new Cell and Gene Therapy (CGT) Access Model that the federal Centers for Medicare & Medicaid Services (CMS) Innovation Center is launching. The initial focus of the federal CGT Access Model will be sickle cell disease. Federal CMS will negotiate outcome-based agreements that also include up-front supplemental drug rebates.

Federal CMS will also monitor, reconcile and evaluate the financial and clinical outcomes tied to outcome-based agreements on behalf of states, and provide federal funding for implementation and expanded access by increasing sickle cell disease specialists and behavioral health providers.

Earlier this month, federal CMS approved a state plan amendment that allows the state of Illinois to negotiate outcomes-based supplemental rebate agreements with drug manufacturers for selected prescription drugs for Medicaid beneficiaries. Under these agreements, HFS and drug manufacturers will agree on patient specific health outcome benchmarks, the methods for evaluating those outcomes, and the rebates that will be provided to the State if those benchmarks are not achieved. With this federal approval, the Illinois Medicaid program is well positioned to implement financing solutions that focus on the health and wellbeing of Illinois Medicaid customers while promoting long-term financial sustainability.

"I appreciate the governor's action to direct greater resources and expand access to sickle cell disease treatments in Illinois," said Assistant Majority Leader Camille Y. Lilly (D-Chicago). "This is an issue that disproportionately affects Black communities, and the sooner we act the sooner we can help to make a positive difference in the lives of many who don't know where to turn because of the high costs of treatment."

"I am pleased the Governor is pulling back the curtain on the longstanding disparities in healthcare and ensuring that all individuals, regardless of their race or background, have equal opportunities for quality treatment and care. This is truly an opportunity to improve the state of our healthcare system, and I'm proud more patients' voices and community partnerships will be prioritized throughout this process," said Rep. Carol Ammons (D-Urbana). "For too long, those in our community, especially our Black, Indigenous, and People of Color (BIPOC) community, have received the short end of

the stick when it comes to equitable access to life-saving treatments. It's time Illinois reaffirms its value to providing access to quality and affordable healthcare for residents statewide."