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Spotlight: Advocate Now to Improve Access to Transformative Cell and Gene Therapies

Without Major Reform to Medicaid Out-of-State Provider Enrollment Requirements, Access to Cell and Gene Therapies May Be Virtually Impossible for Many Beneficiaries

Introduction

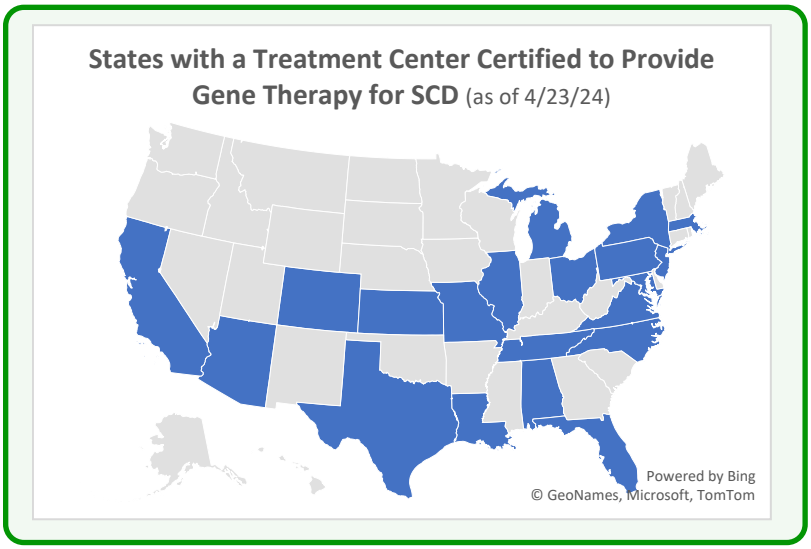
In early 2023, the Centers for Medicare & Medicaid Services (CMS) announced the Cell and Gene Therapy (CGT) Access Model, a program centrally coordinated by the Center for Medicare and Medicaid Innovation (CMMI). The CGT Model seeks to test whether outcomes-based agreements improve access to transformative CGTs for Medicaid beneficiaries.[1] Starting in 2025, the Model will initially focus on gene therapy treatments for beneficiaries living with sickle cell disease (SCD).

While some of the Model's details have been released, a key question remains unanswered: how will beneficiaries receive a gene therapy product if they live in a state without a treatment center (i.e., hospital) which is certified to offer it? The unfortunate reality is that many Medicaid beneficiaries with this devastating and painful genetic blood disorder will face enormous barriers to care due to administrative challenges that prevent centers and providers from enrolling in out-of-state (OOS) Medicaid programs.

CMS has taken a positive first step in developing this Model but, to truly increase access to CGTs, CMMI must address the regulatory and administrative burdens for OOS provider enrollment in Medicaid.

Limited Number of Treatment Centers Means Many Patients Must Travel OOS to Access Care

As of April 2024, Medicaid beneficiaries in over half of country lack access to a treatment center that is certified to provide recently approved gene therapy treatments, which means they will *inevitably be forced* to seek OOS care (see map).[2,3] To do so, they must find a treatment center that is willing to accept them as a patient and also ensure their home state approves the treatment—processes that are complex and lengthy to navigate for everyone involved.



Although more treatment centers are expected to offer these gene therapies by the time CMMI's Model is implemented in 2025, history shows that time alone will not guarantee equitable access for beneficiaries in every state. For example, allogeneic stem cell transplant has been the only curative option for SCD for many decades, but only 28 states provide this treatment today.[4] *Hence, time alone will not solve this problem*.

Current Provider Enrollment Requirements Impact OOS Medicaid Access to Care

In order to be paid by a state's Medicaid program for any services rendered to a Fee-for-Service (FFS) or a managed care organization (MCO) beneficiary, the treatment center and *all* providers involved in a beneficiaries' care MUST be enrolled in the patient's Medicaid program. Providers and centers routinely enroll in their home state's Medicaid program; however, it is administratively impossible to do for all 50 state programs because each functions independently and has its own enrollment requirements. Furthermore, there are no federal requirements mandating timely enrollment; so, even after providers apply for enrollment, beneficiaries could still be forced to wait many months before proceeding with treatment, because the state Medicaid program is still processing the applications.[5]

The risk that providers cannot logistically satisfy these requirements affects all Medicaid beneficiaries seeking OOS care. These requirements are particularly problematic for providers of CGTs, however, due to these treatments' multiple million-dollar costs and complex treatment journeys, which may span more than a year and require copious encounters with numerous providers. For these reasons, most, if not all, centers have internal policies prohibiting treatment for OOS Medicaid beneficiaries unless enrollment in the beneficiaries' state program has been secured beforehand.

Challenges Associated with Providers' Initial Enrollment & Revalidation

- Provider burden: Hours of online training; fingerprinting; criminal background checks; and extensive document submission, such as W9s, copies of licenses, medical school transcripts, and proof of insurance.[5, 6]
- Some state Medicaid programs will not approve a provider's enrollment application until he or she has already billed a claims amount that exceeds a specific monetary threshold. So, a provider might be required to treat a patient and bill for services before they can successfully enroll in the OOS Medicaid program—something that is neither feasible nor realistic for the high price points associated with CGTs.
- Some states terminate providers who have not billed any claims during a 12-month period, forcing them to undertake all the processes required to re-enroll.[6]
- More than 70% of Medicaid beneficiaries are enrolled in an MCO, which often has its own, additional enrollment requirements.[7]

Uniform Provider Enrollment: A Simple Solution to OOS Access to Care

The barriers presented by requirements for OOS provider enrollment in Medicaid programs is not limited to beneficiaries who need gene therapy for SCD. We are focusing on that, however, since CMMI's Model presents an immediate and unique opportunity to pilot a simple solution to this wide-ranging problem.

Nimitt Consulting's proposal is for the CMMI Model to require participating states and their MCOs, if applicable, to accept active enrollment with the Medicare program in lieu of individual state enrollment requirements. Enrollment should be mandated to occur within 30 days of a provider's initial request, or as expeditiously as the beneficiaries' medical condition requires, whichever is shorter. In other words, if the uniform provider enrollment process that Medicare already requires is good enough for Medicare, it should be sufficient for Medicaid, as well. If implemented, our solution would eliminate unnecessary barriers to access and ensure that beneficiaries get the life-saving care they need in a timely manner.

Summary

Provider enrollment requirements are designed to protect program integrity and ensure that Medicaid beneficiaries receive safe care from qualified and eligible providers. But, the reality is that these fragmented, time-consuming, and administratively burdensome requirements create frequently insurmountable access barriers for beneficiaries seeking OOS care. Nimitt believes that CMMI's CGT Model offers a unique opportunity to pilot test a viable way to meet these important objectives and CMS' aim to improve access to transformative CGTS for Medicaid beneficiaries.

Two Ways to Advocate Now!

- Reach out to your Members of Congress (House Representatives and US Senators) to inform them about existing OOS Medicaid enrollment issues and urge them to consider implementation of the Medicare uniform provider enrollment alternative.
- Email CMMI (*CGTModel@cms.hhs.gov*) and explain why the use of the Medicare uniform provider enrollment process should be a requirement for states participating in the Model's pilot.

About Nimitt Consulting, Health Policy Partners | *Nimitt Consulting provides strategic advisory services, education, and data-driven advocacy on health care reimbursement and the factors that drive it. Our unique focus on providers' perspectives and their operational realities enables us to help providers and other stakeholders navigate reimbursement methodologies for innovative treatments, including cell and gene therapies. For more information, please follow us on LinkedIn (www.linkedin.com/company/nimittconsulting/) or contact Susan@Nimitt.com.*

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