

Memorandum

To: Members of the Treatments and Cures Accessibility and Affordability Working Group (AAWG)
From: Rosa Canet-Avilés, Ph.D., CSO
Re: CIRM Access & Affordability – Strategy and Implementation Plan
Date: November 4, 2025

Purpose and Context

Over the past two decades, California has invested in pioneering the discovery and development of transformative cell and gene therapies through CIRM. These investments have brought CIRM to a crucial inflection point: therapies are advancing toward regulatory approval and real-world delivery, yet patients, especially those in underserved and geographically harder to reach communities, still face barriers to access. If CIRM is to fulfill its mission, we must go beyond advancing scientific breakthroughs; we must also ensure that those breakthroughs can reach patients equitably, sustainably, and without delay.

This Access & Affordability (A&A) Strategy was developed in response to that imperative. It provides a framework for how CIRM will enable delivery of CIRM-supported therapies to Californians by integrating clinical infrastructure programs, payer engagement, affordability planning, and partnerships into the full lifecycle of our programs. This strategy represents the next phase of CIRM's evolution from funding innovation to ensuring impact for the people of California. It lays the groundwork for a coordinated system that removes avoidable barriers, collaborates in the advancement of innovative reimbursement pathways, and builds payer and provider readiness so that every therapy developed with taxpayer dollars has a viable path to reach the patients who need it.

The strategy reflects the collective work of CIRM leadership, program experts, infrastructure partners, external advisors, and the guidance of this working group. Today, we ask for your input to help refine this strategic direction before it is brought to the ICOC for consideration as CIRM's implementation roadmap for access and affordability moving forward.

How the Strategy Was Developed

The framework reflects months of structured analysis and dialogue, including:

- **Internal Working Sessions** – Collaborative sessions with the leads of CIRM's Preclinical Development (PDEV), Clinical Development (CDEV), and Clinical Infrastructure teams to assess gaps and realistic levers for impact across the clinical-to-commercial continuum.

- **AAWG Input** – Feedback from AAWG members, particularly AAWG Chair Maria Bonneville emphasizing transparency, and alignment with Proposition 14’s mandates. Her input was central in prioritizing what is actionable, and measurable.
- **Infrastructure and Awardee Experience** – Lessons from Alpha Clinics (ACs), Community Care Centers for Excellence (CCCEs), and the Patient Support Program (PSP) on barriers to trial activation, navigation, and geographic reach.
- **External Consultation** – Insights from external advisors regarding needs for innovative reimbursement models, and opportunities for data-driven payer engagement.

Structure and Key Elements

The strategy is designed to turn the mandates of Proposition 14 to **enhance patient access and promote affordability of CIRM funded therapies** through 3 interconnected objectives, reflecting the need to enhance infrastructure programs, provide access to trials and therapies, drive affordability, and shape policy. Each objective includes key implementation components, actions, outcome metrics, and timelines designed to make progress measurable and operationally feasible. This strategy is grounded in principles that center around equity and real-world impact: it is ambitious, focusing on activities within CIRM’s mandate, integrating access and affordability across existing programs rather than creating separate initiatives and designed to build a statewide system that enables therapies funded by CIRM to be delivered to all eligible Californians, particularly those in underserved and geographically disadvantaged communities.

Following AAWG feedback, the strategy will be refined for presentation to the Board, serving as the baseline for coordinated implementation planning over the next 12–18 months.

I look forward to your guidance and continued partnership as we move this strategy from planning into action.

Requested Action:

CIRM requests a recommendation from the AAWG to advance the draft Access & Affordability Strategy to the ICOC for approval.

Exhibit to Memo: A&A Strategy and Presentation.