

Memorandum

To: Chairman Imbasciani and Members of the ICOC

From: Sean Turbeville, Ph.D., Vice President – Medical Affairs and Policy **Re:** Updates on Proposed Roadmap and Community Care Centers of

Excellence Program

Date: May 31, 2023

Background

Proposition 14 and CIRM's Five-Year Strategic Plan direct CIRM's Medical Affairs and Policy in coordination with the Accessibility and Affordability Working Group (AAWG), to develop a roadmap to overcome access and affordability barriers to CIRM-funded cell and gene therapies. This roadmap will include a strategy for gathering the necessary data and information to support reimbursement for regenerative medicine products that result from CIRM's programs, a plan to engage with policymakers and regulators, and the development of novel healthcare delivery models that can be implemented and refined within the Alpha Clinics Network and future Community Care Centers of Excellence.

Access and Affordability Working Group

The Accessibility and Affordability Working Group was created by Proposition 14 to provide recommendations to the ICOC intended to examine, develop, and assist with the implementation of financial models to enhance the access and affordability of treatments and cures arising from institute-funded research for Californians and to enhance access to clinical trials, including reimbursement alternatives for patient-qualified costs to help achieve the objective that reimbursement covers patient expenses.

Since December 1, 2022, the Medical Affairs and Policy Team has presented several strategies presentations on access and affordability to the AAWG. The topics included strategies to improve reimbursement and limit out-of-pocket expenses for patients participating in CIRM-funded clinical trials; investigating new payer models; researching new state and federal policies and areas where CIRM can expand the clinical infrastructure to improve access and affordability through the Alpha Clinics and future Community Care Centers of Excellence.



The purpose of May 31, 2023, ICOC meeting is to introduce the roadmap to access and affordability through AAWG recommendations in preparation for a final roadmap consideration for the ICOC on June 29, 2023.

Furthermore, we will provide an update on the status of the Community Care Centers of Excellence Program.

No requested action