September 11, 2025

Department of Health Care Services (DHCS)
Medi-Cal Children's Health Advisory Panel (MCHAP)
1700 K Street
Sacramento, CA 95814

Submitted via email to MCHAP@dhcs.ca.gov

RE: MCHAP Meeting September 11, 2025

Dear Chair Mike Weiss, M.D., and Members of the Advisory Panel,

GeneDx appreciates the opportunity to provide comments on the agenda item *Improving Preventive Care Outcomes in Early Childhood*. Founded in 2000 by scientists from the National Institutes of Health, GeneDx was established to meet the needs of patients with rare disorders and the clinicians who care for them. We pioneered the use of exome sequencing (ES) and genome sequencing (GS) for pediatric, rare, and ultra-rare diseases, and quickly became a leader in the field of genomics. Today, GeneDx remains committed to delivering personalized, actionable health insights that inform diagnosis, guide treatment, and accelerate drug discovery, and ultimately, improving health outcomes. Our laboratory in Gaithersburg, Maryland is CLIA-certified, CAP-accredited, and approved by the state of New York.

We commend the California Department of Health Care Services for its responsiveness in establishing a clear and dedicated pathway for requesting coverage of biomarker testing under SB 496 for eligible patients.

The Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program, mandated by the Centers for Medicare & Medicaid Services (CMS), is designed to identify health issues in children early—before they become more complex and costly to treat. It also ensures access to preventive services for Medicaid-eligible children under age 21.[1] As outlined in the federal EPSDT Guide for States, "*When a well-child check-up or other visit to a health care professional shows that a child or adolescent might have a health problem, follow-up diagnostic testing and evaluations must be provided under EPSDT*."[2] The Omnibus Budget Reconciliation Act of 1989 (OBRA '89) further mandates coverage of medically necessary services, even if they are not typically included in a state's Medicaid plan. ES and GS should be available under EPSDT for children with undiagnosed rare diseases; however, access remains challenging.

Despite these federal requirements, the lack of pricing on the Medicaid laboratory fee schedule and the absence of an explicit coverage policy continue to pose significant barriers. Providers may hesitate to order ES or GS, and Medicaid Managed Care Organizations (MCOs) often struggle to adjudicate authorizations and claims efficiently. In many cases, appeals are required

[1] U.S. Code Title 42 § 1396d(r) – Definition of Early and Periodic Screening, Diagnostic, and Treatment Services.
[2] Centers for Medicare & Medicaid Services. (2024). SHO #24-005: Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements. https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf

to secure coverage. A clear coverage policy for ES and GS would streamline access to these critical diagnostic tools for the children who need them most.

Importantly, in June, the American Academy of Pediatrics updated its guidance to recommend ES and GS as first-tier tests for children with global developmental delay or intellectual disability in most cases, citing superior diagnostic yield and cost-effectiveness when used early in the diagnostic process.[3]

Including ES and GS in the Medicaid fee schedule and coverage policy under SB 496 and EPSDT will empower pediatricians to deliver earlier diagnoses, initiate timely interventions, and improve outcomes for children in California. Early use of ES and GS not only enhances clinical outcomes but also reduces costs across the healthcare system.[4],[5]

GeneDx looks forward to collaborating with the Department through the newly established pathway to ensure coverage and reimbursement for ES and GS under both SB 496 and EPSDT. Should you have any questions or concerns, please contact me at theresa.andrews@genedx.com.

Sincerely,

Original Signed by

Theresa Andrews
Director, Government Affairs
GeneDx

At GeneDx, we believe that everyone deserves personalized, targeted medical care—and that it all begins with a genetic diagnosis. Fueled by one of the world's largest rare disease data sets, our industry-leading exome and genome tests translate complex genomic data into clinical answers that unlock personalized health plans, accelerate drug discovery, and improve health system efficiencies. It all starts with a single test.

For more information, please visit GeneDx.com and connect with us on LinkedIn, X, Facebook, and Instagram.

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[3] Rodan LH, Stoler J, Chen E, Geleske T; Council on Genetics . Genetic Evaluation of the Child With Intellectual Disability or Global Developmental Delay: Clinical Report. Pediatrics. 2025;156(1):e2025072219. doi:10.1542/peds.2025-072219

[4] Lavelle TA, Feng X, Keisler M, et al. Cost-effectiveness of exome and genome sequencing for children with rare and undiagnosed conditions. Genet Med. 2022;24(6):1349-1361. doi: 10.1016/j.gim.2022.03.005.

[5] Manickam K, McClain MR, Demmer LA, et al. Exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability: an evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2021;23(11):2029-2037. doi:10.1038/s41436-021-01242-6