SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: AB 114
AUTHOR: Maienschein
VERSION: May 24, 2021
HEARING DATE: June 16, 2021
CONSULTANT: Kimberly Chen

SUBJECT: Medi-Cal benefits: rapid Whole Genome Sequencing

SUMMARY: Requires rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, to be a covered benefit for any Medi-Cal beneficiary who is one year old or younger and is receiving inpatient hospital services in an intensive care unit.

Existing law:
1) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which low-income individuals are eligible for medical coverage. [WIC §14000, et seq.]

2) Establishes a schedule of benefits in the Medi-Cal program, including coverage of Medi-Cal in patient services reimbursed based on diagnosis related groups (DRGs). Establishes a schedule of benefits in the Medi-Cal program, including coverage of durable medical equipment (DME). Requires DHCS to establish maximum allowable reimbursement rates for DME and specify utilization controls for each type of DME. [WIC §14132, 14105.48]

This bill:
1) Requires rapid Whole Genome Sequencing (RWGS), including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, to be a covered benefit for any Medi-Cal beneficiary who is one year old or younger and is receiving inpatient hospital services in an intensive care unit (ICU).

2) Authorizes DHCS to implement, interpret, or make specific this subdivision by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions until the time regulations are adopted.

FISCAL EFFECT: According to the Assembly Appropriations Committee, unknown, likely minor potential cost pressure to Medi-Cal associated with specifying RWGS as a Medi-Cal benefit (General Fund/federal funds).

COMMENTS:
1) *Author's statement.* According to the author, Project Baby Bear demonstrated that rapid whole genome sequencing has the potential to provide parents and doctors with vital information to determine the course of treatment for critically ill infants. The benefits that this testing can provide to so many families of infants with rare diseases are extraordinary. By ensuring that testing is a covered Medi-Cal benefit, California can achieve significant healthcare cost savings and families can shorten their search for answers in how to optimally care for their children.

2) *Whole genome sequencing*. Whole genome sequencing is a method used by health care professionals to evaluate a person's entire genome to identify mutations that may be responsible for a health condition. Rapid refers to the length of time to receive test results. The human genome is made up of all of an individual's genes, which contain DNA. A person's DNA contains the genetic coding to produce proteins, which are the building blocks of tissues and which carry out a multitude of functions. A genetic disorder occurs when a there is a mutation in a gene that results in improper functioning. Gene mutations do not always have severe health implications; it depends on where they occur and what essential proteins are impacted.

3) *Project Baby Bear*. The Budget Act of 2018 (SB 840, Mitchell, Chapter 29, Statutes of 2018) appropriated $2 million for the RWGS Pilot Project, known as Project Baby Bear. It required DHCS to provide a grant to a state nonprofit organization for a one-time pilot project to investigate the potential clinical and programmatic value of utilizing RWGS in the Medi-Cal program. The results of this pilot program are available in the Project Baby Bear Final Report provided to the State but are not yet published in a peer-reviewed format. According to California Health Benefits Review Program (CHBRP), Project Baby Bear enrolled 178 infants (aged less than 1 year) who were hospitalized and in ICUs with unexplained critical illnesses. All 178 infants received RWGS and of those, 76 (43%) resulted in a diagnosis. The diagnoses led to a change in care for 55 infants (31% of overall sample; 72% of those with a diagnosis), including changes to medication, treatments, and procedures, as well as discontinuing futile care. To model reductions in health care utilization, a retrospective analysis was performed on a sample of 29 infants from this program for whom RWGS resulted in significant clinical benefit. This analysis estimated that use of RWGS in this sample of 29 infants resulted in 16 fewer invasive diagnostic tests, 11 fewer major surgeries, and 454 to 573 fewer hospitalization days in total.

4) *CHBRP analysis*. AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996, and reviewed this bill. Key findings include:

   a) *Benefit coverage*. DHCS considers genetic testing a lab test that is already a covered benefit for Medi-Cal beneficiaries. RWGS used to diagnose children 1 year of age or younger in an ICU is already included in the existing all-inclusive inpatient diagnosis related group (DRG) or per diem payment hospitals receive from Medi-Cal managed care plans, Medi-Cal fee-for-service (FFS), or California Children's Services (CCS).

   b) *Medical effectiveness*. Though the Project Baby Bear findings did not meet CHBRP's requirements for inclusion in the medical effectiveness grading, CHBRP found a preponderance of evidence shows that RWGS is effective at providing diagnoses for ill infants with diseases of unknown cause, resulting in a higher diagnostic rate than other standard genetic tests and a faster turnaround time to diagnosis. CHBRP states there is limited evidence showing that RWGS improved clinical utility in the treatment of ill infants in an ICU who received a diagnosis, including more precise care management and reduced hospitalization.

c) *Cost impact*. At baseline, 100% of beneficiaries with Medi-Cal coverage that would be subject to this bill have coverage for RWGS delivered in an ICU setting. CHBRP's analysis found no claims or encounters paid during 2019 for RWGS or other genetic tests delivered to Medi-Cal beneficiaries in an ICU, suggesting that DHCS is not paying separately for RWGS, whole exome sequencing, other gene sequencing, or other genetic tests.

5) *Support*. This bill is sponsored by Rady Children's Hospital – San Diego. They state that RWGS is a single, comprehensive tool historically employed as a last resort test. More recently, it has become a front-line test physicians utilize to provide rapid diagnoses to their sickest patients. The purpose of RWGS is to find genetic changes that are causing a child's symptoms. They argue that Project Baby Bear demonstrated that using RWGS as a first-line test for critically ill Medi-Cal babies improved clinical outcomes, improved the experience of care for families and clinicians, and reduced net healthcare expenditures.

   This bill is also supported by Children's Specialty Care Coalition, which writes that this bill builds on a successful pilot project known as Project Baby Bear, which was funded by the state in 2018, and sought to demonstrate that a rapid precision medicine program for critically ill Medi-Cal babies improves clinical outcomes, improves the experience of care, and reduces net healthcare expenditures. They state that the pilot project led to quicker diagnoses and answers for families about their infant's condition, enabling swifter and appropriate treatment. It also meant fewer unnecessary and invasive procedures, and less time spent in the hospital. They conclude that this bill would ensure that critically ill infants in the ICU who are covered by Medi-Cal have this chance to more effectively and expeditiously identify and appropriately treat their condition.

6) *Policy comment*. RWGS is currently covered in Medi-Cal as hospital patient services reimbursed based on diagnosis related groups (DRGs). The sponsor of this bill state that the existing process for seeking coverage approval for RWGS can take up to five days after submission. This bill would require RWGS be available to all beneficiaries who meet the criteria specified in the bill.

SUPPORT AND OPPOSITION:

Support: Rady Children's Hospital - San Diego (sponsor)
Biotechnology Innovation Organization
California Children's Hospital Association
California Chronic Care Coalition
California Life Sciences Association
Children's Hospital of Orange County
Children's Specialty Care Coalition
Rady Children's Institute for Genomic Medicine
UCSF Benniоff Children's Hospital Intensive Care Nursery
Valley Children's Healthcare
One Individual

Oppose: None received

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