

ASSEMBLY THIRD READING
AB 114 (Maienschein)
As Amended May 24, 2021
Majority vote

SUMMARY

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 Medi-Cal covered benefit for any Medi-Cal beneficiary who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit (ICU).

Major Provisions

Requires the Department of Health Care Services to implement, interpret, or make specific this bill by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions until the time regulations are adopted.

COMMENTS

The Budget Act of 2018 (SB 840 (Mitchell), Chapter 29, Statutes of 2018) appropriated \$2 million for the Whole Genome Sequencing Pilot Project, and required DHCS, through budget bill language, 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. Whole genome sequencing is a method used 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. This pilot was known as Project Baby Bear and ended in June 2020.

Project Baby Bear enrolled 178 infants who were hospitalized and in ICUs at one of five pilot sites with unexplained critical illnesses. All 178 infants received RWGS and of those, 76 (43%) resulted in a diagnosis. The median time to receive provisional results was reported to be three days, with 31.5% of the cases analyzed using ultra-rapid whole genome sequencing. 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.

According to the Author

Project Baby Bear demonstrated that RWGS 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. The author concludes that, by ensuring that testing is a covered Medi-Cal benefit, California can achieve significant health care cost savings and families can shorten their search for answers in how to optimally care for their children.

Arguments in Support

This bill is sponsored by Rady Children's Hospital – San Diego (Rady Children's), which writes 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. RWGS quickly reads through the entire human genome (roughly 22,000 genes or "instructions") and looks for changes that are causing the child's illness. With this information, physicians are able to provide medical care based on the molecular diagnosis, allowing for more precise medications and treatments to be directed to the patient. Project Baby Bear was a California demonstration project that utilized RWGS in the intensive care setting for patients under one year of age. The project 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. Of the 178 patients that received sequencing, 76 patients (43%) received a diagnosis that explained the cause of their hospitalization. In addition, 55 patients (31%) had a change in management that led to fewer hospital days, fewer procedures, or more appropriate therapies and medications. Rady Children's concludes that adding RWGS to the list of Medi-Cal covered benefits will not only save the lives of many babies and change how they are able to live the rest of their lives, but will make the test available to all babies who need it by adding it to the list of Medi-Cal covered benefits.

Arguments in Opposition

There is no known opposition.

FISCAL COMMENTS

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).

VOTES

ASM HEALTH: 15-0-0

YES: Wood, Mayes, Aguiar-Curry, Bigelow, Bonta, Burke, Carrillo, Flora, Maienschein, McCarty, Nazarian, Chiu, Rodriguez, Santiago, Waldron

ASM APPROPRIATIONS: 16-0-0

YES: Lorena Gonzalez, Bigelow, Calderon, Carrillo, Chau, Megan Dahle, Davies, Fong, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, Holden, Luz Rivas

UPDATED

VERSION: May 24, 2021

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