

Date of Hearing: April 21, 2021

ASSEMBLY COMMITTEE ON APPROPRIATIONS

Lorena Gonzalez, Chair

AB 114 (Maienschein) – As Amended April 5, 2021

Policy Committee: Health Vote: 15-0

Urgency: No State Mandated Local Program: No Reimbursable: No

SUMMARY:

This bill adds Rapid Whole Genome Sequencing (rWGS), as specified, as 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.

It also carves the new rWGS benefit out of the existing diagnosis-related group-based (DRG) Medi-Cal reimbursement methodology and specifies the benefit shall be reimbursed in addition to, and separate from, a DRG payment.

FISCAL EFFECT:

If 250 babies are tested annually at an average cost of \$9,750 per test, about \$2.5 million annually to Medi-Cal (GF/federal). According to DHCS, there are 209,885 children enrolled in Medi-Cal under age 1 year; the California Health Benefits Review Program (CHBRP) estimates based on prevalence that approximately 250 of these children would be born with a genetic condition. If more babies are tested or if costs per test decrease, costs could be higher or lower commensurate with such changes.

COMMENTS:

- 1) **Purpose.** According to the author, a state-funded pilot study of rWGS of critically ill infants demonstrated the value of rWGS in diagnosing and changing the course of treatment for these infants. The author believes the benefit should therefore be added to the schedule of Medi-Cal benefits and separately reimbursed to account for the high cost of the test.
- 2) **Background.** Genome sequencing is a laboratory test designed to identify and analyze the sequence of DNA. Various sequencing tests are available. If a particular disease is suspected, a clinician may order a specific genetic test. If a genetic basis for a disease is suspected without a specific clinical indication, a clinician may opt for whole genome sequencing to search the entire genome for abnormalities that may be responsible for a health condition.

This bill specifies rWGS is a covered Medi-Cal service for qualifying infant, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing. According to CHBRP's report on this bill, rWGS of an individual generally takes 11 days, while ultra-rapid sequencing takes an average of 5.5 days. Trio sequencing examines either the whole or partial genomes of the infant and the parents, which can improve diagnostic results.

CHBRP found a preponderance of evidence from eight studies that rWGS is effective at providing diagnoses for ill infants with diseases of unknown cause. These studies provided

substantial evidence that rWGS resulted in a higher diagnostic rate than other standard genetic tests and provided a faster turnaround time to diagnosis.

- 3) **Current Coverage.** DHCS considers rWGS to be a laboratory test and, therefore, Medi-Cal covers genetic testing when medically necessary as part of the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for Medi-Cal beneficiaries under 21 years of age.
- 4) **Pilot Project.** The Budget Act of 2018, SB 840 (Mitchell), Chapter 29, Statutes of 2018, appropriated \$2 million for the Whole Genome Sequencing Pilot Project. 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 pilot, known as Project Baby Bear, concluded in June 2020. According to the final report published by Rady Children's Hospital, five clinical sites demonstrated implementing rWGS for critically ill infants who met inclusion criteria in the study improves clinical outcomes, improves the experience of care for families and clinicians, and reduces net healthcare expenditures by avoiding unnecessary procedures and reducing length of stay. According to the report, preliminary results from the genome sequencing were available within about three days.
- 5) **DRG Reimbursement.** Prior to implementing the DRG reimbursement methodology in 2010, Medi-Cal hospital inpatient reimbursement was based on audits of actual hospital costs or on a contracted per diem rate. The DRG reimbursement methodology was considered a reform to the way Medi-Cal reimburses hospitals. Also used by Medicare and in other countries, the DRG reimbursement methodology categorizes similar diagnoses into groups and establish a single reimbursement rate for the group. It is based on studies of costs for treating various conditions and recognizes that the resource intensity of hospital services varies by diagnoses. It also avoids the complexity of paying for a large number of individual services and incentivizes shorter hospital lengths of stay by providing a single payment regardless of the length of stay. DRG payments are adjusted by DHCS annually to account for changes in cost of care on a relative basis, but the changes must be budget-neutral on an overall basis.
- 6) **Staff Comment.** DHCS indicates coverage for rWGS is already provided to infants covered by Medi-Cal when medically necessary. In addition, the DRG payment is designed to be inclusive of diagnostic tests and other clinical services, per a specified diagnosis, raising a question of whether a legislative exemption from inclusion in the DRG payment for one specific test is appropriate. There may be a rationale for certain high-cost tests, procedures or the like to be excluded from a DRG payment, but legislating specific exemptions may result in increased complexity that, over time, may limit administrative flexibility to respond to the constantly evolving context of hospital services and payments. It also risks creating a precedent for additional legislative exemptions from DRG payments for other services, undermining the comprehensive nature of DRG payments.

Analysis Prepared by: Lisa Murawski / APPR. / (916) 319-2081