Key Findings

Analysis of California Assembly Bill 114
Medi-Cal Benefits: Rapid Whole Genome Sequencing

Summary to the 2021–2022 California State Legislature, March 27, 2021

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

SUMMARY

The version of California Assembly Bill (AB) 114 analyzed by CHBRP would expand the Medi-Cal schedule of benefits to include rapid whole genome sequencing (rWGS), including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, for any Medi-Cal beneficiary who is 1 year of age or younger receiving inpatient hospital services in an intensive care unit (ICU). AB 114 would be relevant to the benefit coverage of the subset of Medi-Cal beneficiaries who are 1 year of age or younger receiving care in an ICU.

Benefit Coverage: The Department of Health Care Services (DHCS) considers genetic testing a lab test that is already a covered benefit for Medi-Cal beneficiaries. Rapid whole genome sequencing 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). AB 114 would not result in new benefit coverage that exceeds the definition of essential health benefits (EHBs) in California.

Medical Effectiveness: 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. 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.

Cost and Health Impacts[1]: At baseline, 100% of beneficiaries with Medi-Cal coverage that would be subject to AB 114 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.

AB 114 would have no impact on Medi-Cal expenditures because it is already a covered benefit under current law for 100% of Medi-Cal beneficiaries 1 year of age or younger who would be in an ICU bed.

CHBRP estimates AB 114 would produce no measurable public health impact due to no projected change in coverage. CHBRP did not find evidence to suggest that AB 114 would impact utilization of rWGS differentially by race/ethnicity, gender, income, or geography and so projects no impact on these disparities related to genetic disorders and clinical outcomes.

It is expected that AB 114 would result in no long-term utilization impacts, cost impacts, or public health impacts.

CONTEXT

The Budget Act of 2018 (SB 840) appropriated $2,000,000 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 rapid whole genome sequencing (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.[2] This pilot was known as Project Baby Bear and ended in June 2020. It provided rWGS to babies aged less than 1 year of age enrolled in Medi-Cal who were receiving intensive care at one of five pilot sites. The results of this pilot program are available in the Project Baby Bear Final Report provided to the State.

[1] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

[2] Refer to CHBRP's full report for full citations and references.

BILL SUMMARY

AB 114 would expand the Medi-Cal schedule of benefits to include rapid whole genome sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, for any Medi-Cal beneficiary who is 1 year of age or younger and is receiving inpatient hospital services in an intensive care unit (ICU).

AB 114 would be relevant to the benefit coverage of the subset of Medi-Cal beneficiaries age 1 year or younger receiving care in an ICU. These beneficiaries can be enrolled in health plans regulated by the Department of Managed Health Care (DMHC), in County Organized Health Systems (COHS), or be primarily associated with Medi-Cal's fee-for-service (FFS) program.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, 100% of beneficiaries with Medi-Cal coverage that would be subject to AB 114 have coverage for rWGS or an equivalent service delivered in an ICU setting.

According to DHCS payment policy for inpatient services delivered through Medi-Cal Managed Care plans, Medi-Cal FFS, or the California Children's Services (CCS) program, rWGS is already covered through the diagnosis related group (DRG) or per diem payment for those inpatient stays.

Utilization

CHBRP used data from Medi-Cal encounters and claims data from Milliman to assess baseline utilization and estimate postmandate utilization. There were no claims or encounters paid during 2019 for rWGS or other genetic tests delivered to Medi-Cal or CCS beneficiaries in an ICU. This analysis provides evidence to suggest that DHCS is not paying separately for rWGS, whole exome sequencing, other gene sequencing, or other genetic tests. As stated above, the DRG and per diem payments used to reimburse different hospitals by Medi-Cal and CCS are all-inclusive, meaning that lab services such as rWGS would not result in an additional payment or claim.

Although individual genetic tests provided during a hospital stay in an ICU are not identifiable through claims analyses, it is possible for physicians to order the tests to facilitate diagnosis and treatment of their patients. In the case of rWGS, physicians may be required to request approval from hospital administrators to order the test. However, if hospitals are concerned about the relative cost of the test due to the level of DRG or per diem reimbursement available for an ICU patient covered by Medi-Cal or CCS, they might not approve providers' requests to order rWGS. The hospitals' current DRG or per diem rate in Medi-Cal or CCS for that inpatient stay would not change based on the number or type of tests ordered since these rates are intended to cover necessary tests. Due to the all-inclusive nature of the inpatient DRG or per diem rate, laboratory and genetic tests delivered in an inpatient setting are not reimbursed separately by Medi-Cal Managed Care plans, Medi-Cal FFS, or CCS.

Expenditures

AB 114 would not change total net annual expenditures for beneficiaries 1 year of age or younger with Medi-Cal Managed Care, CCS, or other Medi-Cal FFS coverage. AB 114 would have no impact on Medi-Cal expenditures because it is already a covered benefit under current law for 100% of Medi-Cal and CCS beneficiaries 1 year of age or younger who would be in an ICU bed.

Although CHBRP estimates that Medi-Cal expenditures for rWGS would not change, it is possible that hospitals paying for rWGS to facilitate early diagnoses of genetic disorders would spend less on the provision of clinical care during the ICU stay. Depending on circumstances and severity of illness, hospitals receiving an all-inclusive DRG or per diem rate may have an incentive to authorize use of rWGS to speed up the diagnostic process or increase efficiency.

CHBRP estimates that administrative costs would not change for Medi-Cal Managed Care plans, Medi-Cal FFS, or CCS due to AB 114.

Medical Effectiveness

CHBRP found a preponderance[3] 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

[3] *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

genetic tests and provided a faster turnaround time to diagnosis.

CHBRP found limited[4] evidence that rWGS is effective at improving clinical utility in the treatment of ill infants receiving care in an ICU. Results from six studies provided limited evidence that rWGS improved clinical utility in the treatment of those who received a diagnosis, including more precise care management and reduced hospitalization. There were several limitations that contributed to the gradings provided, most notably the inherent barriers to conducting strong comparative research designs within a population of critically ill infants, resulting in a literature base that is not as rigorous and thereby limiting the certainty of conclusions drawn from the evidence.

Public Health

There is a preponderance of evidence that rWGS is effective at providing diagnoses and limited evidence that it is effective at improving clinical utility, indicating that for critically ill infants and their families, rWGS could lead to improvements to or affirmation of the care plan. However, because there is no projected change in coverage, CHBRP estimates AB 114 would produce no measurable public health impact at the population level.

Disparities in the prevalence and detection of genetic disorders exist; however, CHBRP did not find evidence to suggest that AB 114 would impact utilization of rWGS differentially by race/ethnicity, gender, income, or geography. CHBRP projects no impact on these disparities related to genetic disorders and clinical outcomes.

Long-Term Impacts

No long-term utilization or cost impacts are expected due to current coverage for rWGS in the existing inpatient DRG or per diem payment made by Medi-Cal Managed Care plans, Medi-Cal FFS, or CCS. Because CHBRP estimates no change in utilization, it is not anticipated that AB 114 would result in any long-term public health impacts.

Essential Health Benefits and the Affordable Care Act

Benefit coverage of Medi-Cal beneficiaries is not subject to the same set of essential health benefits (EHBs) as the benefit coverage of enrollees in nongrandfathered small-group and individual market plans and policies. AB 114 would not result in new benefit coverage that exceeds the definition of EHBs in California.

[4] *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.