Rady Children's Institute® Genomic Medicine

Emerging Healthcare Plan Coverage for Rapid Whole Genome Sequencing™

The New Standard of Care

Multiple studies have shown that rapid Whole Genome Sequencing™ (rWGS®) can empower clinicians to make timely, precise diagnoses and treatment decisions for critically ill children with genetic diseases. For infants with rare conditions of unknown etiology, rWGS® can provide actionable, molecular diagnoses, enabling cost-effective patient care. Demonstrated benefits of rWGS® include expedited reporting of critical results, clinical certainty, improved outcomes, reduced costs and peace of mind for patient families.

Rising Reimbursement

Opportunities are emerging for reimbursement of rWGS®. Already, Blue Cross Blue Shield in nine states (California, Florida, Idaho, Hawaii, New Jersey, Louisiana, Michigan, Mississippi and New York-Northeastern and Western plans) have adopted policies determining that rWGS® is medically necessary for critically ill children in Intensive Care Units with disorders of unknown etiology (Table 1).[1] In addition, state Medicaid program policies cover rWGS®, including Michigan Medicaid, as of September 2021, and California Medi-Cal, as of January 2022.[1]

Table 1: Coverage and Policies for rWGS®

STATE	POLICY	POLICY NUMBER	DATE ACTIVE	COVERAGE	INCLUSION CRITERIA
CA	Blue Cross Blue Shield	2.04.102	May 2019	rWGS® or rWES	• Critically ill infants or children less than 18 years of age • Hospitalized in neonatal or pediatric intensive care with illness of unknown etiology • At least one of the following: multiple congenital anomalies, specific malformations highly suggestive of a genetic etiology, an abnormal laboratory test suggests a genetic disease or complex metabolic phenotype, an abnormal response to standard therapy for a major underlying condition, significant hypotonia, persistent seizures, infant with high risk stratification on evaluation for a Brief Resolved Unexplained Event (BRUE) • Exclusion criteria detail in policy
CA	Medi-Cal	N/A	January 2022	rWGS®	Up to 1 year of age or younger receiving inpatient care in intensive care unit
FL	Florida Blue	05-82000-28	May 2020	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
ID	Blue Cross Idaho	2.04.102	June 2020	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
HI	Hawaii Medical Service Association	MM.02.035	September 2020	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
LA	Blue Cross Blue Shield Louisiana	00389	January 2021	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
MI	Blue Cross Blue Shield Michigan	Not listed	March 2021	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
MI	Medicaid	MSA 21-33	September 2021	rWGS®	• Up to 1 year age in NICU/PICU with unknown etiology • Suspected genetic condition that cannot be Dx by standard workup • Dx would require ordering of multiple genetic tests • Requiring timely Dx and at least one apply: multiple congenital anomolies, specific malformations, abnormal lab, severe hypoglycemia, abnormal response to a therapy, severe hypotonia, refractory seizures, BRUE, abnormal chem suggestive of IBEM, abnormal cardiac Dx testing, family genetic history related to patient.
MS	Blue Cross Blue Shield Mississippi	A.2.04.102	May 2021	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
NJ	Horizon Blue New Jersey	094	May 2021	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
NY	Blue Shield Northeastern New York	204102	March 2021	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
NY	Blue Cross Blue Shield Western New York	204102	June 2021	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]
	Blue Cross Blue Shield Federal Employee Program	2.04.201	July 2020	rWGS® or rWES	Similar to Blue Shield of California, refer to policy[1]

Clinical Utility and Cost Savings

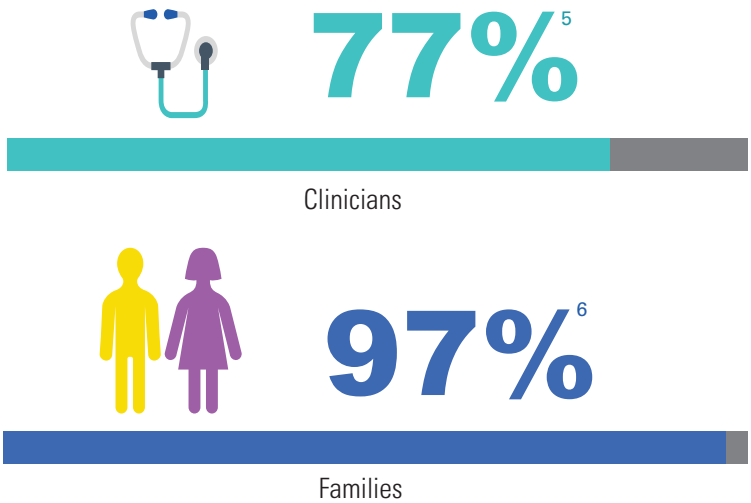
Annually, an estimated 60,000 children who could benefit from rWGS® are admitted to neonatal, pediatric or cardiovascular intensive care units.[2] In clinical studies, rWGS® has been shown to provide a diagnosis in 35% of cases, change in treatment in 27% and change in outcome for 17%.[3] Additionally, rWGS® can yield a substantial reduction in healthcare costs by eliminating the need for unnecessary tests, procedures and surgeries, and allowing for precision care and earlier hospital discharge.

Findings from California's Project Baby Bear® were modeled to show that if rWGS® were used to identify or rule out genetic disease for the pool of 60,000 children who might benefit, potential savings could total up to $200M in yearly medical costs.[4]

Clinicians and Families Both Value rWGS®

In a 2020 study, 77% of clinicians and 97% of families felt rWGS was beneficial,[5] despite a diagnostic rate of 23%, demonstrating that even a negative genome result provides useful clinical information (Figure 1).[6] Families reported that if given the opportunity, they would make the same decision and move forward with genome sequencing for their child.[6]

Figure 1. Support for the use of rWGS



Getting Started with rWGS®

For most commercial and government payors, providing supplementary reimbursement for an inpatient genetic test is not yet standard. To identify the key infrastructure and resources required to provide rWGS® as a reimbursed clinical diagnostic test, RCIGM led a pilot project. We uncovered key elements to be considered with respect to inpatient ordering, authorization, electronic record integration, billing. Important lessons learned regarding internal authorization and resource allocation processes are detailed below (Table 2). This information is intended to guide clinicians and administrators to navigate the hospital system, enabling access of rWGS® for patients.

Transforming Healthcare Today

The power to improve lives through Rapid Precision Medicine™ is here. Public and commercial payors are increasingly defining rWGS® as medically necessary. Improved patient outcomes and quality of life are now possible through cost-effective, precision care. Let us help you adopt the new standard of care.

Ready to Get Started?

Contact RCIGM for resources on rWGS® to share with decision makers within your institution.

858.966.8127
ask@RadyGenomics.org

Table 2: Quick Guide to Implementing rWGS®

THINGS TO KNOW– FOR CLINICIANS

First Steps

- Obtain family consent.
- Work with your laboratory for the sample collection. Contact us for a sample collection kit.
- Complete the Test Requisition form by email, fax, or utilizing the Clinical Genomics Center Portal.
- Package and ship the specimens. https://radygenomics.org/order-test/
- Automate through your EMR system (Ask us how!).

Billing Authorization

- Varies by Payor, in some cases you have up to 30 days after the data of service to submit.
- Relevant CPT Codes:
    - Proband (Patient)
        - PLA Code 0094U or CPT Code 81425
- Trio and Ultra-Rapid
    - PLA Code 0094U or CPT Code 81425
    - CPT Code 81426 (Parent #1)
    - CPT Code 81426 (Parent #2)

Reimbursement Options

- Multiple State and Commercial options are available as described in Table 1.
- Many rWGS inpatients' cost of care will exceed stop loss or outlier thresholds and accordingly result in % of charges reimbursement based upon individual payor contract terms.

For detailed information, please contact us at ask@RadyGenomics.org

References:

1. The following Blue Shield and/or Blue Cross state plans include coverage for rapid Whole Genome Sequencing:
   Blue Shield of California (May 2019) https://www.blueshieldca.com/bsca/bsc/public/common/PortalComponents/provider/StreamDocumentServlet?fileName=PRV_WholeExome_Sequen.pdf
   Florida Blue (May 2020) http://mcgs.bcbsfl.com/MCG?mcgId=05-82000-28&pv=false
   Blue Cross of Idaho (June 2020) https://providers.bcidaho.com/resources/pdfs/medical-management/Medical%20Policy%20PDF/2%20-%20Med/02.04.102_03-25-21.pdf
   Hawaii Medical Service Association - An independent licensee of Blue Cross and Blue Shield Assn. (September 2020) https://cdn1-originals.webdamdb.com/14017_108318950?cache=1625095834&response-content-disposition=inline;filename=MM.02.035_Whole_Exome_and_Whole_Genome_Sequencing_for_Diagnosis_of_Genetic_Disorders_2021-0528.pdf&response-content-type=application/pdf&Policy=eyJTdGF0ZW1lbnQiOlt7IlJlc291cmNlIjoiaHR0cCo6Ly9jZG4xLW9yaWdpbmFscy53ZWJkYW1kYi5jb20vMTQwMTdfMTA4MzE4OTUwP2NhY2hlPTE2MjUwOTU4MzQmcmVzcG9uc2UtY29udGVudC1kaXNwb3NpdGlvbj1pbmxpbmU7ZmlsZW5hbWU9TU0uMDIuMDM1X1dob2xlX0V4b21lX2FuZF9XaG9sZV9HZW5vbWVfU2VxdWVuY2luZ19mb3JfRGlhZ25vc2lzX29mX0dlbmV0aWNfRGlzb3JkZXJzXzIwMjEtMDUyOC5wZGYmcmVzcG9uc2UtY29udGVudC10eXBlPWFwcGxpY2F0aW9uL3BkZiIsIkNvbmRpdGlvbiI6eyJEYXRlTGVzc1RoYW4iOnsiQVdTOkVwb2NoVGltZSI6MjE0NzQxNDQwMH19fV19&Signature=hyjK-JRSwmEqguvRbkxG5PknSbGRxi5JtirVw6nT6PgxN2TZWM9pWNZ4O0FsFEKNUn7avxA2OlUkUbjN6Fpqni2E8GENc8k-EF2jkjqTJNopAylycbhippcPJToA4dB99dhFkE-ePnoF~JcxwLjTO5qY3K07HRiPR2Nt0tQjt8Sh7Sh9xfuly3S2abFluh-6EIPh96o5UmiI7oJ9UsgPiV17Rog3ytWalktdkeZws4aKyw2ace34hmWVHztvuq9g66U-uUqmmgOyvuu73Wz491EyscSty7LsernSGj9lqaNVBuoe6UR3Qt8B3Suj82aQYOEVWlcXwMmmU3m~8sijtA__&Key-Pair-Id=APKAI2ASI2IOLRFF2RHA
   Blue Cross Blue Shield Louisiana (January 2021) https://www.bcbsla.com/-/media/Medical%20Policies/2020/08/03/17/36/WholeExomeandWholeGenomeSequencingforDiagnosisofGeneticDisorders.pdf
   Blue Cross Blue Shield Michigan (March 2021) https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/2034822.pdf
   Blue Cross Blue Shield Mississippi (May 2021) https://www.bcbsms.com/medical-policy-search#/policy-detail?id=6a9931dd-4769-44e9-86e3-690fe0dfd2f7
   Horizon Blue New Jersey (May 2021) https://www.horizonblue.com/providers/policies-procedures/policies/medical-policies/detail/dac88083-74b7-7488-37d6-2209a0452261
   Blue Shield Northeastern New York (March 2021) https://www.bsneny.com/content/dam/COMMON/non-secure/provider/Protocols/W/prov_prot_204102.pdf
   Blue Cross Blue Shield Western New York (June 2021) https://www.bcbswny.com/content/dam/COMMON/non-secure/provider/Protocols/W/prov_prot_204102.pdf
   Blue Cross Blue Shield Federal Employee Program (July 2020) https://www.fepblue.org/-/media/PDFs/Medical%20Policies/07-10-2020/204102%20Whole%20Exome%20and%20Whole%20Genome%20Sequencing.pdf
   The following Medicaid state plans include coverage for rapid Whole Genome Sequencing:
   Michigan Medicaid (September 2021) https://www.michigan.gov/documents/mdhhs/2131-Lab-P_728798_7.pdf
   Medi-Cal (January 2022) https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220AB133; Originally put forth as AB 114, included in the general health bill: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB114
2. Lobo, I. & Zhaourova, K (2008) Birth defects: causes and statistics. *Nature Education* 1(1):13
3. The Evidence is In: Rapid Whole Genome Sequencing is the new Standard of Care for Acutely Ill Infants. (2021) Rady Children's Institute for Genomic Medicine
4. Based on Project Baby Bear, the total cost of sequencing 178 genomes was $1.737 million and saved $2.489 million in unnecessary healthcare costs. This amounted to $1.43 savings for every $1 spent. Extrapolating data out to 60,000 genomes, total cost savings is ~$0.8 billion. Project Baby Bear was a quality improvement project (Nov. 2018 – May 2020) funded by the State of California that sequenced the genomes of 178 children admitted at five children's hospitals statewide. Participants were acutely ill Medi-Cal beneficiaries, under one year of age.
5. Dimmock DP, Clark MM, Gaughran M, et al. An RCT of Rapid Genomic Sequencing among Seriously Ill Infants Results in High Clinical Utility, Changes in Management, and Low Perceived Harm. *Am J Hum Genet.* 2020;107(5):942-952. doi:10.1016/j.ajhg.2020.10.003
6. Cakici JA, Dimmock DP, Caylor SA, et al. A Prospective Study of Parental Perceptions of Rapid Whole-Genome and -Exome Sequencing among Seriously Ill Infants. *Am J Hum Genet.* 2020;107(5):953-962. doi:10.1016/j.ajhg.2020.10.004

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