SENATE
STATE OF MINNESOTA
NINETY-THIRD SESSION

S.F. No. 2445

(SENATE AUTHORS: MORRISON and Coleman)

DATE	D-PG	OFFICIAL STATUS
03/02/2023	1277	Introduction and first reading Referred to Commerce and Consumer Protection
04/02/2024	13339	Author added Coleman

A bill for an act

relating to insurance; requiring a health carrier to provide coverage for rapid whole genome sequencing; proposing coding for new law in Minnesota Statutes, chapter 62A.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62A.3098] RAPID WHOLE GENOME SEQUENCING; COVERAGE.**

Subdivision 1. **Definition.** For purposes of this section, "rapid whole genome sequencing" or "rWGS" means an investigation of the entire human genome, including coding and noncoding regions and mitochondrial deoxyribonucleic acid, to identify disease-causing genetic changes that returns the preliminary positive results within five days and final results in 14 days. Rapid whole genome sequencing includes patient-only whole genome sequencing and duo and trio whole genome sequencing of the patient and the patient's biological parent or parents.

Subd. 2. **Required coverage.** A health plan that provides coverage to Minnesota residents must cover rWGS testing if the enrollee:

(1) is 21 years of age or younger;

(2) has a complex or acute illness of unknown etiology that is not confirmed to have been caused by an environmental exposure, toxic ingestion, an infection with a normal response to therapy, or trauma; and

(3) is receiving inpatient hospital services in an intensive care unit or a neonatal or high acuity pediatric care unit.

Subd. 3. **Coverage criteria.** Coverage may be based on the following medical necessity criteria:

(1) the enrollee has symptoms that suggest a broad differential diagnosis that would require an evaluation by multiple genetic tests if rWGS testing is not performed;

(2) timely identification of a molecular diagnosis is necessary in order to guide clinical decision making, and the rWGS testing may aid in guiding the treatment or management of the enrollee's condition; and

(3) the enrollee's complex or acute illness of unknown etiology includes at least one of the following conditions:

(i) congenital anomalies involving at least two organ systems, or complex or multiple congenital anomalies in one organ system;

(ii) specific organ malformations that are highly suggestive of a genetic etiology;

(iii) abnormal laboratory tests or abnormal chemistry profiles suggesting the presence of a genetic disease, complex metabolic disorder, or inborn error of metabolism;

(iv) refractory or severe hypoglycemia or hyperglycemia;

(v) abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems;

(vi) severe muscle weakness, rigidity, or spasticity;

(vii) refractory seizures;

(viii) a high-risk stratification on evaluation for a brief resolved unexplained event with any of the following features:

(A) a recurrent event without respiratory infection;

(B) a recurrent seizure-like event; or

(C) a recurrent cardiopulmonary resuscitation;

(ix) abnormal cardiac diagnostic testing results that are suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease;

(x) abnormal diagnostic imaging studies that are suggestive of underlying genetic condition;

(xi) abnormal physiologic function studies that are suggestive of an underlying genetic etiology; or

(xii) family genetic history related to the patient's condition.

Subd. 4. **Cost sharing.** Coverage provided in this section is subject to the enrollee's health plan cost-sharing requirements, including any deductibles, co-payments, or coinsurance requirements that apply to diagnostic testing services.

Subd. 5. **Reimbursement.** If the enrollee's health plan uses a capitated or bundled payment arrangement to reimburse a provider for services provided in an inpatient setting, reimbursement for services covered under this section must be paid separately and in addition to any reimbursement otherwise payable to the provider under the capitated or bundled payment arrangement, unless the health carrier and the provider have negotiated an increased capitated or bundled payment rate that includes the services covered under this section.

Subd. 6. **Genetic data.** Genetic data generated as a result of performing rWGS and covered under this section: (1) must be used for the primary purpose of assisting the ordering provider and treating care team to diagnose and treat the patient; (2) is protected health information as set forth under the Health Information Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health Act, and any promulgated regulations, including but not limited to the HIPAA Privacy Rule under Code of Federal Regulations, title 45, parts 160 and 164, subparts A and E; and (3) is a protected health record under the Minnesota Health Records Act under section 144.291.

EFFECTIVE DATE. This section is effective January 1, 2024, and applies to a health plan offered, issued, or sold on or after that date.