Ohio Revised Code

Section 5164.093

Effective: September 30, 2025
Legislation: House Bill 96

(A) As used in this section, "rapid whole genome sequencing" means an investigation of the entire human genome, including coding and non-coding regions and mitochondrial deoxyribonucleic acid, to identify disease-causing genetic changes, and includes patient-only whole genome sequencing and duo and trio whole genome sequencing of the patient and biological parent or parents.

(B) Beginning one year after the effective date of this section, and subject to approval from the centers for medicare and medicaid services, the medicaid program shall reimburse medicaid providers for rapid whole genome sequencing for patients who are Medicaid recipients and meet all of the following criteria:

(1) The patient is under one year of age.

(2) The patient has a complex or acute illness of unknown etiology that is not confirmed to be caused by an environmental exposure, toxic ingestion, infection with normal response to therapy, or trauma.

(3) The patient is receiving hospital services in an intensive care unit or other high acuity care unit within a hospital.

(C) A laboratory performing the rapid whole genome sequencing provided pursuant to this section shall return the preliminary positive results within seven days and final results within fifteen days from the date of receipt of the sample.

(D) Payment provided pursuant to this section may be subject to any of the following evidence-based medical necessity criteria:

(1) The patient has symptoms that suggest a broad differential diagnosis that would require an evaluation by multiple genetic tests if rapid whole genome sequencing is not performed.

(2) The patient's treating health care provider has determined that timely identification of a molecular diagnosis is necessary to guide clinical decision-making and testing results may guide the treatment or management of the patient's condition.

(3) The patient has a family genetic history related to the patient's condition.

(4) The patient has a complex or acute illness of unknown etiology including at least one of the following conditions:

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

(b) Specific organ malformations highly suggestive of a genetic etiology;

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

(d) Refractory or severe hypoglycemia or hyperglycemia;

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

(f) Severe muscle weakness, rigidity, or spasticity;

(g) A high-risk stratification for a brief, resolved, unexplained, and recurrent event that is any of the following:

(i) An event without respiratory infection;

(ii) A witnessed seizure-like event;

(iii) A cardiopulmonary resuscitation event.

(h) Refractory seizures;

(i) Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis,or structural heart disease;

(j) Abnormal diagnostic imaging studies suggestive of an underlying genetic condition;

(k) Abnormal physiologic function studies suggestive of an underlying genetic etiology.

(E) The director may add conditions to those specified in division (D)(4) of this section based on new medical evidence and may provide coverage for rapid whole genome sequencing or other next-generation sequencing and genetic testing in addition to the reimbursement required under this section.

(F)(1) Except as provided in division(F)(2) of this section, genetic data generated as a result of performing rapid whole genome sequencing pursuant to this section shall have a primary use of assisting the ordering health care professional and treating care team to diagnose and treat the patient, and as protected health information it shall be subject to the requirements applicable to protected health information set forth in the "Health Insurance Portability and Accountability Act of 1996," 42 U.S.C. 1320d et seq., the "Health Information Technology for Economic and Clinical Health Act of 2009," 42 U.S.C. 17921 et seq., and any other applicable law regarding protected health information.

(2) Genetic data generated from rapid whole genome sequencing reimbursed under this section can be used in scientific research if consent for such use of the data has been expressly given by the patient's legal guardian. The patient, the patient's legal guardian, or the patient's health care provider with the patient or the patient's guardian's consent, may request access to the results of the testing for use in other clinical settings. A health care provider may only charge a fee to the patient based on the direct costs of producing the results in a format usable in other clinical settings. A patient or a patient's legal guardian shall have the right to rescind the original consent to the use of the data in scientific research at any time, and upon receipt of a written revocation of the consent the health care provider or other entity using the data shall cease use and expunge the data from any data repository where it is held.

(G) The director shall take any actions necessary to implement the provisions of this section, including:

(1) Adopting rules authorized by section 5166.02 of the Revised Code;

(2) Any other administrative action determined to be necessary to implement the requirements of this section.