STATE OF NEW YORK

9324

IN ASSEMBLY

February 29, 2024

Introduced by M. of A. PAULIN -- read once and referred to the Committee on Health

AN ACT to amend the social services law, in relation to payment for rapid whole genome sequencing

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The social services law is amended by adding a new section 367-y to read as follows:

§ 367-y. Payment for rapid whole genome sequencing. 1. For purposes of 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 that returns the preliminary positive results within seven days and final results within fifteen days from the date of receipt of the sample by the lab performing the test. "Rapid whole genome sequencing" includes patient-only whole genome sequencing and duo and trio whole genome sequencing of the patient and biological parent or parents.

2. One year after the effective date of this section, and subject to any required approval of the Centers for Medicare and Medicaid Services, the commissioner shall authorize the payment of medical assistance funds for rapid whole genome sequencing when the beneficiary:

(a) is under twenty-one years of age;

(b) 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; and

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

3. Payment provided pursuant to this section may be subject to applicable evidence-based medical necessity criteria that shall be based on all of the following:

(a) 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;

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD13237-02-4

(b) the patient's treating healthcare 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; and

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

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

(ii) specific organ malformations 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:

(A) a recurrent event without respiratory infection;

(B) a recurrent witnessed seizure-like event; or

(C) a recurrent cardiopulmonary resuscitation event;

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

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

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

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

4. The commissioner may add conditions to those contained in paragraph (c) of subdivision three of this section based upon new medical evidence and may provide coverage for rapid whole genome sequencing or other next generation sequencing and genetic testing in addition to the coverage required under this section.

5. (a) Except as provided in paragraph (b) of this subdivision, genetic data generated as a result of performing rapid whole genome sequencing covered 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 as set forth in the Health Information Portability and Accountability Act ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, their attendant regulations, including but not limited to the HIPAA Privacy Rule as promulgated at 45 CFR Part 160 and Subparts A and E of 45 CFR Part 164, and any applicable state or local law.

(b) Genetic data generated from rapid whole genome sequencing, covered pursuant to this section, can be used in scientific research if consent for such use of the data has been expressly given by the patient, or the patient's legal guardian in the case of a minor. The patient, the patient's legal guardian in the case of a minor, or the patient's health care provider with the patient's consent, may request access to the results of the testing covered by this section 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 patient's legal guardian in the case of a minor, 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.

6. The commissioner shall take any actions necessary to implement the provisions of this section, including, but not limited to:

(a) promulgating rules and regulations to provide for payment pursuant to this section;

(b) submitting to the Centers for Medicare and Medicaid Services any new waiver application, amendment to an existing waiver, or Medicaid state plan amendment necessary to ensure federal financial participation for Medicaid coverage pursuant to this section; and

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

§ 2. This act shall take effect immediately.