REFERENCE TITLE: AHCCCS; rapid genome sequencing

State of Arizona
House of Representatives
Fifty-sixth Legislature
First Regular Session
2023

HB 2470

Introduced by
Representative Montenegro

AN ACT

AMENDING TITLE 36, CHAPTER 29, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING SECTION 36-2907.16; RELATING TO THE ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Title 36, chapter 29, article 1, Arizona Revised Statutes, is amended by adding section 36-2907.16, to read:

36-2907.16. Rapid whole genome sequencing; coverage requirements; rules; administrative action; definition

A. SUBJECT TO ANY REQUIRED APPROVAL OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, THE ADMINISTRATION AND ITS CONTRACTORS SHALL PROVIDE COVERAGE OF RAPID WHOLE GENOME SEQUENCING AS A SEPARATELY PAYABLE SERVICE FOR MEMBERS IF THE MEMBER MEETS ALL OF THE FOLLOWING CRITERIA:

1. IS UNDER ONE YEAR OF AGE.

2. 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. IS RECEIVING INPATIENT HOSPITAL SERVICES IN AN INTENSIVE CARE UNIT OR A HIGH ACUITY PEDIATRIC CARE UNIT.

B. THE COVERAGE PROVIDED PURSUANT TO THIS SECTION MAY BE SUBJECT TO APPLICABLE EVIDENCE-BASED MEDICAL NECESSITY CRITERIA THAT ARE BASED ON ANY OF THE FOLLOWING:

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 DETERMINES THAT TIMELY IDENTIFICATION OF A MOLECULAR DIAGNOSIS IS NECESSARY TO GUIDE CLINICAL DECISION-MAKING AND THAT TESTING RESULTS MAY GUIDE THE TREATMENT OR MANAGEMENT OF THE PATIENT'S CONDITION.

3. 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 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) AN ABNORMAL RESPONSE TO THERAPY RELATED TO AN UNDERLYING MEDICAL CONDITION AFFECTING VITAL ORGANS OR BODILY SYSTEMS.

(f) SEVERE MUSCLE WEAKNESS, RIGIDITY OR SPASTICITY.

(g) REFRACTORY SEIZURES.

(h) A HIGH-RISK STRATIFICATION ON EVALUATION FOR A BRIEF RESOLVED UNEXPLAINED EVENT WITH ANY OF THE FOLLOWING:

(i) A RECURRENT EVENT WITHOUT RESPIRATORY INFECTION.

(ii) A RECURRENT SEIZURE-LIKE EVENT.

(iii) A RECURRENT CARDIOPULMONARY RESUSCITATION.

(i) ABNORMAL CARDIAC DIAGNOSTIC TESTING RESULTS SUGGESTIVE OF POSSIBLE CHANNELOPATHIES, ARRHYTHMIAS, CARDIOMYOPATHIES, MYOCARDITIS OR STRUCTURAL HEART DISEASE.

(j) ABNORMAL DIAGNOSTIC IMAGING STUDIES OR PHYSIOLOGIC FUNCTION STUDIES SUGGESTIVE OF AN UNDERLYING GENETIC CONDITION OR ETIOLOGY.

(k) FAMILY GENETIC HISTORY RELATED TO THE PATIENT'S CONDITION.

C. GENETIC DATA GENERATED AS A RESULT OF PERFORMING RAPID WHOLE GENOME SEQUENCING THAT IS COVERED PURSUANT TO THIS SECTION:

1. SHALL HAVE A PRIMARY USE OF ASSISTING THE ORDERING HEALTH CARE PROFESSIONAL AND TREATING CARE TEAM TO DIAGNOSE AND TREAT THE PATIENT.

2. PROTECTED HEALTH INFORMATION THAT IS SUBJECT TO THE REQUIREMENTS APPLICABLE TO PROTECTED HEALTH INFORMATION AS SET FORTH IN THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT, AND THEIR ATTENDANT REGULATIONS, INCLUDING THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT PRIVACY STANDARDS (45 CODE OF FEDERAL REGULATIONS PART 160 AND PART 164, SUBPARTS A AND E).

D. THE DIRECTOR SHALL SUBMIT ANY NEW WAIVER APPLICATION, AMENDMENT TO AN EXISTING WAIVER OR MEDICAID STATE PLAN AMENDMENT NECESSARY FOR APPROVAL FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES FOR COVERAGE OF RAPID WHOLE GENOME SEQUENCING AS PRESCRIBED IN THIS SECTION. THE DIRECTOR MAY ADOPT ANY RULES OR TAKE ANY OTHER ADMINISTRATIVE ACTION NECESSARY TO IMPLEMENT THIS SECTION.

E. FOR THE PURPOSES OF THIS SECTION, "RAPID WHOLE GENOME SEQUENCING":

1. MEANS AS AN INVESTIGATION OF THE ENTIRE HUMAN GENOME, INCLUDING CODING AND NONCODING REGIONS AND MITOCHONDRIAL DEOXYRIBONUCLEIC ACID, THAT IDENTIFIES DISEASE-CAUSING GENETIC CHANGES AND THAT RETURNS THE PRELIMINARY POSITIVE RESULTS WITHIN FIVE DAYS AND FINAL RESULTS WITHIN FOURTEEN DAYS.

2. INCLUDES PATIENT-ONLY WHOLE GENOME SEQUENCING AND DUO AND TRIO WHOLE GENOME SEQUENCING OF THE PATIENT AND THE PATIENT'S BIOLOGICAL PARENT OR PARENTS.