Medical Policy

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders**
Policy Number	**2.02.46**
Category	**Technology Assessment**
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Archived Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, whole exome sequencing (WES), with trio testing when possible, may be considered **medically appropriate** for the evaluation of unexplained congenital or neurodevelopmental disorder in children younger than 21 years, when **ALL** of the following criteria are met:

A. A genetic cause is the most likely explanation for the phenotype despite previous genetic testing (eg, chromosomal microarray analysis and/or targeted single-gene testing) as shown by **TWO** of the following:

1. abnormality affecting a single organ system;
2. significant developmental or intellectual delay, symptoms of a complex neurodevelopmental disorder, and/or severe neuropsychiatric condition;
3. family history strongly suggesting a genetic etiology;
4. period of unexplained developmental regression;
5. inability to explain symptoms by other causes, such as environmental exposure, injury or infection; or
6. biochemical findings suggestive of an inborn error of metabolism; AND

B. **ONE** of the following indications applies:

1. The clinical presentation does not fit a single well-described syndrome, or may describe two or more syndromes making WES more practical than separate single gene tests or panels; or
2. The affected individual is faced with invasive procedures or testing as the next diagnostic step (eg, muscle biopsy); AND

C. **ALL** of the following indications apply:

1. Medical record documentation reflects that the patient has been evaluated by a clinician with expertise in clinical genetics, and includes at minimum, a family history and phenotype description, and that the patient has been counseled about the potential risks of genetic testing; and

2. The diagnosis cannot be established or confirmed by standard clinical work-up; and
3. There is potential for a change in management and clinical outcome for the patient being tested.

II. Based upon our criteria and assessment of the peer-reviewed literature, whole genome sequencing (WGS) is considered **investigational** for the diagnosis of genetic disorders.

III. Based upon our criteria and assessment of the peer-reviewed literature, whole exome sequencing (WES) and whole genome sequencing (WGS) are considered **investigational** for prenatal diagnosis or preimplantation testing of an embryo.

IV. Based upon our criteria and assessment of the peer-reviewed literature, genetic testing using an epigenetic assay (e.g., EpiSign (Greenwood Genomic Center, Greenwood SC)), is considered **investigational** for the diagnosis of genetic disorders.

POLICY GUIDELINES

I. The Health Plan and its employees adhere to all state and federal laws concerning the confidentiality of genetic testing and the results of genetic testing. All records, findings and results of any genetic test performed on any person shall be deemed confidential and shall not be disclosed without the written informed consent of the person to whom such genetic test relates. This information shall not be released to any person or organization not specifically authorized by the individual subject of the test.

II. Whole exome sequencing, or WES and whole genome sequencing, or WGS, should only be offered in a setting with adequately trained health care providers (e.g., a medical geneticist or an affiliated genetic counselor) to provide appropriate pre-and post-test genetic counseling that will guide decisions regarding treatment options.

III. The EpiSign assay (Greenwood Genomic Center, Greenwood SC) is a methylation assay designed to readily identify proven and reproducible epigenetic signatures by assessing genome-wide methylation and can detect multiple methylation abnormalities in over 50 genes and disorders.

IV. The option to receive secondary findings should be offered regardless of the age of the patient. Informed consent should be obtained based on the recommendations of the American College of Medical Genetics and Genomics (ACMG).

V. Laboratories performing clinical tests must be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

VI. If the genetic test is being performed for knowledge only and that knowledge will not alter the management or treatment of the patient or family member(s) then the testing is considered not medically appropriate.

Refer to Corporate Medical Policy #2.02.03 Genetic Testing for Inherited Disorders

Refer to Corporate Medical Policy #2.02.42 Chromosomal Microarray (CMA) Analysis for the Prenatal Evaulation and Evaluation of Patients with Developmental Delay/Intellectual Disability or Autism Spectrum Disorder

Refer to Corporate Medical Policy #4.01.03 Preconception and Prenatal Genetic Testing/Counseling and Preimplantation Genetic Diagnosis (PGD)

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

DESCRIPTION

Diagnostic confirmation of an individual with features suggestive of an inheritable disease (Mendelian disorder) may include traditional molecular and conventional diagnostic tests which may still yield an inconclusive clinical diagnosis after exhaustive and expensive testing. These individuals may be candidates for WES or WGS. WES and WGS utilize next-generation or massively parallel sequencing technology that allows multiple genes to be analyzed at one time and may return a pathogenic variant that is associated with a gene-causing disease. WGS processes genomic DNA (both coding and non-coding portions of the gene) followed by a series of computational analyses to determine the sequence of

the sample DNA as compared to a reference DNA sequence. WGS is able to evaluate about 90% of the genome. WES is targeted sequencing of the subset of the human genome that contains functionally important sequences of the protein-coding DNA. It comprises approximately 1.5% of the genome and contains approximately 85% of highly penetrant genetic disease DNA variations. To perform WES testing, the genomic DNA is hybridized to artificial DNA which is then sequenced similarly to WGS. Approximately 85-90% of the exome is covered by WES with less effective coverage in the non-protein-coding portion of the genes. Standards for testing methods, reporting of results, and interpretation of results as well as social and ethical questions are areas where additional research is still needed before whole genome or exome sequencing can be incorporated into clinical practice.

Whole genome or whole exome sequencing results include three distinct categories: a variant known to cause human diseases, a variant suspected of causing human disease, and a variant of uncertain significance. Standards, or algorithms still need to be developed to ensure accuracy in the interpretation of results, continuing assessment of gene variants, and explore ethical issues. Studies have identified technical difficulties in reproducing and confirming variations by another second testing method. Identification of genetic variants and their significance relies on the database that is used. Current databases are inconsistent with variable information, and there is no set standard for updating these databases. There is no standardization in the approach of reporting incidental findings to individuals or the implications of reporting benign or catastrophic disease. More research is needed, to expand databases and to standardize test methods and the interpretation and reporting of results, before whole exome and whole genome sequencing should be incorporated into clinical practice, rather than used as a research tool.

Whole exome sequencing has led to the emergence of more than 50 disorders that have been classified as Mendelian disorders, with several of these disorders exhibiting unique genome-wide DNA methylation profiles, known as episignatures. The episignatures are part of a field of study, called epigenetics, which refers to changes in gene expression without altering the primary DNA sequence. Epigenetic modifications include the attachment or removal of a methyl on a cytosine base or an acetyl group a lysine residue from a histone protein. For the purposes of the type of testing included in this policy, the focus of the epigenetic changes will be on DNA methylation. DNA methylation involves the addition of a methyl group (CH_3), almost exclusively to carbon 5 in a cytosine base, to create 5-methylcytosine. Common sites for DNA methylation are at the promoter or enhancer regions of the affected gene. The addition of the methyl group often prevents transcription or “silences” the gene. DNA hypomethylation involves removing of one or more methyl groups from the cytosine base, which may activate expression of a gene that was previously silenced. Epigenetic changes may be a result of imprinting (specific maternal or paternal gene regulation), from environmental effects on health (e.g., starvation or obesity, stress, smoke, and air pollution), and toxin exposure or ingestion of toxic molecules (e.g. pesticides, plastics, cosmetics). Even though there is a disruption in causative genetic variants in distinct genes, phenotypes in multiple disorders may overlap, making it difficult to make a definitive diagnosis. Common features of the disorders caused by epigenetic changes include intellectual disability, growth defect, and immune dysfunction.

The EpiSign assay (Greenwood Genetic Center, Greenwood, SC), per the Genetic Center website, is an assay designed to readily identify proven and reproducible epigenetic signatures by assessing genome-wide methylation. The assay is a comprehensive analysis of more than 50 genes and disorders and can detect multiple methylation abnormalities associated with certain imprinting or triplet repeat conditions, as well as identifying disease-specific methylation patterns involving multiple loci across the genome. The assay determines an episignature, a highly sensitive and specific diagnostic biomarker in an increasing number of chromatinopathies, which allows for distinguishing affected from unaffected individuals, disease-causing from non-disease-causing variants. In addition, the assay assesses the functional significance of variations of unknown significance (VUSs), leading to reclassification where applicable. An advantage to the EpiSign assay is that it utilizes a sample from the patient only and the results do not rely on testing of other family members.

RATIONALE

Published exome sequencing studies show that the technology can be used to detect previously cataloged pathogenic mutations and reveal new likely pathogenic mutations in known and unknown genes. In addition, WES appears to have a

higher diagnostic yield, to have quicker return of results, and to be more efficient compared to traditional Sanger sequencing.

The American College of Medical Genetics (ACMG) has stated that diagnostic testing with WES (and WGS) should be considered in the clinical diagnostic assessment of a phenotypically affected individual when:

I. The phenotype or family history data strongly implicate a genetic etiology, but the phenotype does not correspond with a specific disorder for which a genetic test targeting a specific gene is available on a clinical basis.
II. A patient presents with a defined genetic disorder that demonstrates a high degree of genetic heterogeneity, making WES or WGS analysis of multiple genes simultaneously a more practical approach.
III. A patient presents with a likely genetic disorder but specific genetic tests available for that phenotype have failed to arrive at a diagnosis.
IV. A fetus has a likely genetic disorder, but specific genetic tests, including targeted sequencing tests, available for that phenotype have failed to arrive at a diagnosis.

The ACMG recommends that WGS/WES may be considered in preconception carrier screening, using a strategy to focus on genetic variants known to be associated with significant phenotypes in homozygous or hemizygous progeny.

The ACMG also recommends that WGS/WES should not be used at this time as an approach to prenatal screening, or as a first-tier approach for newborn screening.

In March 2013, an ACMG board finalized approval of its recommendations for reporting incidental findings in WGS and WES. A working group determined that reporting some incidental findings would likely have medical benefit for the patients and families of patients undergoing clinical sequencing. The group recommended that, when a report is issued for clinically indicated exome and genome sequencing, a minimum list of conditions, genes, and variants be routinely evaluated and reported to the ordering clinician.

In 2021, Miller et al. published the ACMG's updated recommendations for reporting of secondary finding in clinical exome and genome sequencing. In addition to policy updates and recommendations by the ACMG's Secondary Finding Maintenance Working Group (SFWG), they announced plans to update the list of actionable secondary findings annually. According to the statement, "*the option to receive secondary findings should be offered regardless of the age of the patient. The best interest of the child should still be prioritized when disclosing risk for adult-onset conditions in minors*."

Many summary articles and reviews have been published regarding the use of epigenetics in describing and diagnosing neurodevelopmental and certain Mendelian disorders. However, the mechanistic understanding of multigenerational phenotypes and DNA methylation are still not clearly defined. Further studies and improved methods are needed to explain mechanisms of action of environmental factors, gene-environment interactions, and multigenerational effects. The results of these studies may expand our knowledge and help to identify biomarkers and risk factors for disease and improve diagnostic and treatment practices. Currently there are no Medical Society Guidelines recommending testing for episignatures in these disorders.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
81404	Molecular Pathology Procedure Level 5
81405	Molecular Pathology Procedure Level 6

Code	Description
81406	Molecular Pathology Procedure Level 7
81407	Molecular Pathology Procedure Level 8
81408	Molecular Pathology Procedure Level 9
81415	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81416	Exome (e.g, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)
81417	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)
81425 (E/I)	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426 (E/I)	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g, parents, siblings) (List separately in addition to code for primary procedure)
81427 (E/I)	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g, updated knowledge or unrelated condition/syndrome)
0036U	Exome (i.e., somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses (e.g., EXaCT-1 Whole Exome Testing)
0094U (E/I)	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis (e.g., RCIGM Rapid Whole Genome Sequencing; Rady Children's Institute for Genomic Medicine)
0209U (E/I)	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities (CNGnome, PerkinElmer Genomics)
0213U (E/I)	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling) (Do not report 0213U in conjunction with 81426) (Genomic Unity® Whole Genome Analysis – Comparator; Variantyx Inc)
0214U (E/I)	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband (Do not report 0212U in conjunction with 81415) (Genomic Unity® Whole Genome Analysis – Proband; Variantyx Inc)

Code	Description
0215U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (eg, parent, sibling) (Do not report 0215U in conjunction with 81416) (Genomic Unity® Exome Plus Analysis – Comparator; Variantyx Inc.)
0260U (E/I)	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping (August Optical Genome Mapping, Georgia Esoteric and molecular (GEM) Laboratory, LLC, Bionano Genomics, Inc)
0264U (E/I)	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping (Praxis Optical Genome Mapping, Praxis Genomics LLC)
0265U (E/I)	Rare constitutional and other heritable disorders, whole genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants (Praxis Whole Genome Sequencing, Praxis Genomics LLC)
0267U (E/I)	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole genome sequencing (Praxis Combined Whole Genome Sequencing and optical Genome Mapping, Praxis Genomics LLC)
0318U (E/I)	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood (EpiSign Complete, Greenwood Genetic Center) (Effective 4/1/2022)
0335U (E/I)	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants (IriSight™ Prenatal Analysis – Proband, Variantyx, Inc (*Effective 10-2-2022*)
0336U (E/I)	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg,parent) (IriSight™ Prenatal Analysis – Comparator, Variantyx, Inc (*Effective 10-1-22*)
0417U	Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder-associated genetic variants *(effective 10/01/2023)*

Code	Description
0425U **(E/I)**	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings) *(effective 01/01/24)*
0426U **(E/I)**	Genome (eg, unexplained constitutional or heritable disorder or syndrome), ultra-rapid sequence analysis *(effective 01/01/24)*

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
Numerous Diagnoses	

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*Key Article

KEY WORDS

Exome, genome, WES, WGS

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Molecular Pathology Procedures. Please refer to the following LCD website for Medicare members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35000&ver=133&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=Active&bc=AggAAAQAgAAA&

There is currently a Local Coverage Article (LCA) for Molecular Pathology Procedures. Please refer to the following LCA website for Medicare members: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56199&ver=62&LCDId=35000&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=Active&bc=AggAAAQAgAAA&=