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Whole Exome and Whole Genome Sequencing MP9548

Covered Service: Yes

Prior Authorization Required: Yes

Additional Information: Genetic testing is covered for a Prevea360 Health Plan member if the test results provide a direct medical benefit or guides reproductive decision-making for the Prevea360 Health Plan member. See Genetic Testing MP9012 for additional information.

Pre- and post-test genetic counseling is required for any individual undergoing genetic testing for whole exome sequencing.
A first-degree relative is defined as an individual's parents, full siblings, and children.
A second-degree relative is defined as an individual's grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings.
A third-degree relative is defined as first cousins, great-aunts, great-uncles, great-grandchildren, or great-grandparents.

Prevea360 Health Plan Medical Policy:

1.0 Whole Exome Sequencing (WES) **requires prior authorization** through the Health Services Division and is considered medically necessary for a phenotypically-affected individual less than 21 years of age when **ALL** of the following criteria are met:

- 1.1 Individual has been evaluated by a board-certified medical geneticist or other board certified specialist with specific expertise in the conditions and relevant genes for which testing is being considered; **AND**
- 1.2 WES results will directly impact clinical-decision making and clinical outcomes for the individual being tested (e.g. including withholding contraindicated treatments or palliative care); **AND**
- 1.3 A genetic etiology is the most likely explanation for the phenotype as demonstrated by **ANY** of the following:
  - 1.3.1 Multiple abnormalities affected unrelated organ systems
  - 1.3.2 The differential diagnosis list and/or phenotype warrant testing of multiple genes and **ANY** of the following:

1.3.2.1 WES is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis

1.3.2.2 WES results may preclude the need for multiple and/or invasive procedures, follow-up or screening that would be recommended in the absence of testing.

1.3.3 Known or suspected early-onset or infantile epileptic encephalopathy (onset before three (3) years of age)

1.3.4 Individual with confirmed bilateral sensorineural hearing loss of unknown etiology

1.3.5 Two of the following criteria are met:

1.3.5.1 Abnormality affecting at a minimum a single organ system

1.3.5.2 Significant developmental delay, intellectual disability, symptoms of a complex neurodevelopmental disorder (e.g. self-injurious behavior, revers sleep-wake cycles), or severe neuropsychiatric condition (e.g. schizophrenia, bipolar disorder, Tourette syndrome)

1.3.5.3 Family history strongly suggestive of a genetic etiology

1.3.5.4 Period of unexplained developmental regression (unrelated to autism or epilepsy)

1.3.5.5 Biochemical findings suggestive of an inborn error of metabolism

1.3.6 No other causative circumstances (e.g. environmental exposures, injury, infection) can explain symptoms

2.0 Comparator (parents, siblings) exome sequence analysis **requires prior authorization** through the Health Services Division and is considered medically necessary when the criteria in (1.0) have been met and WES is being performed concurrently or has been previously performed.

3.0 Genetic testing for heritable disorders of a Prevea360 Health Plan member's non-Prevea360 Health Plan relative **requires prior authorization** through the Health Services Division. Testing is considered medically necessary for exome sequencing of an affected child's mother and/or father (trio testing) if (1.0) criteria (whole exome sequencing) is met and **ANY** of the following clinical situations:

3.1 Determination of a clinical diagnosis in an affected individual who has a suspected genetic condition that routine genetic testing has been unable to identify

3.2 Individual's medical history and physical exam findings strongly suggest that there is an underlying genetic etiology

3.3 Identification a gene in an individual with an undiagnosed genetic syndrome

3.4 Reoccurrence risk assessment

4.0 WES testing in the general population is considered not medically necessary.

5.0 Whole Genome Sequencing (WGS) is considered experimental and investigational and therefore not medically necessary, including but not limited to the following:

5.1 Evaluation of fetal demise

5.2 Molecular profiling of tumors for the diagnosis, prognosis or management of cancer

5.3 Prenatal genetic diagnosis or screening

CPT/HCPCS Codes Related to MP9548

The list of codes (and their descriptors, if any) is provided for informational purposes only and may not be all inclusive or current. Listing of a code in this medical policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with Prevea360 Health Plan. Inclusion of a code above does not imply any right to reimbursement or guarantee claim payment. Other medical policies may also apply.

CPT Code	Description
0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s) (e.g. MicroGenDX qPCR and NGS for Infection)
0013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)
0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)
0036U	Exome (i.e., somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses
0094U	Genome (e.g., unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities (e.g. CNGome)
0212U	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,

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CPT Code	Description
	blood or saliva, identification and categorization of genetic variants, proband
0213U	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)
0214U	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, proband
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)
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 (e.g., 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 (e.g., updated knowledge or unrelated condition/syndrome)
81425	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	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	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)

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CPT Code	Description
81460	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed
81479	Unlisted molecular pathology procedure

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