Medica Coverage Policy

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<th>Policy Name:</th>
<th>Genetic Testing for Epilepsy and Seizure Disorders</th>
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<td>Effective Date:</td>
<td>10/15/2018</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Genetic testing for epilepsy and seizure disorders is investigative and unproven, and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: Please also see related Medica coverage policies; Whole Exome Sequencing, Whole Genome Sequencing, and Genetic and Pharmacogenetic Testing.

Description

Epilepsy is a neurologic disorder characterized by the predisposition of unprovoked and recurrent seizures, with approximately 3% of the population developing the disorder over their entire lifespan. It encompasses many different types of seizures that vary in age of onset and severity. Epilepsy has a variety of causes, including trauma, infection, structural brain anomalies, metabolic diseases, environmental factors, and genetic disorders. While a significant proportion of epilepsy in childhood has genetic, metabolic, or congenital structural basis, epilepsy diagnosed in adults is more likely to be due to an acquired vascular, degenerative, or neoplastic etiology.

The genetic basis of epilepsy is complex and virtually all chromosomal syndromes can manifest seizures. The common genetic epilepsies are primarily believed to involve multifactorial inheritance patterns. This follows the concept of a threshold effect, in which any particular genetic defect may increase the risk of epilepsy, but is not by itself causative. A combination of risk-associated genes, together with environmental factors, determines whether the clinical phenotype of epilepsy occurs. However, it is not well understood how many abnormal genes are required to exceed the threshold to cause clinical epilepsy, nor is it understood which combination of genes may increase the risk more than others. Genetic epilepsies also include a number of rare monogenic epileptic disorders that occur in infancy or early childhood (e.g., Dravet syndrome) and that may be caused by a single gene pathogenic variant. These rare syndromes account for less than 1% of all inherited epilepsies.

Epilepsy is generally chronic, requiring treatment with anti-epileptic medications in most cases, but some patients are resistant to medications and further options such as surgery, vagus nerve stimulation, and/or the ketogenic diet can be used. At present most genetic findings have no immediate influence on patient management.
FDA Approval
The U.S. Food and Drug Administration (FDA) does not regulate or review genetic tests. Commercially-available genetic tests are regulated under the auspices of the Clinical Laboratory Improvement Amendments (CLIA). Laboratories that offer laboratory developed tests (LDTs) must be licensed by CLIA for high-complexity testing.

Genetic testing for epilepsy is commercially available from numerous companies. These panels typically include large numbers of genes that may or may not be associated with primary epilepsy. Examples of commercially available genetic panels for epilepsy include:

1. Emory Genetics® Epilepsy and Seizure Disorders Sequencing panel (109 genes).
2. GeneDx®: Infantile Epilepsy Panel (53 genes); Childhood-Onset Epilepsy Panel; Comprehensive Epilepsy Panel (70 genes).
3. MNG XpressTM Actionable Epilepsy Panel (69 genes).
5. Athena Diagnostics Epilepsy Advanced Sequencing Evaluation (234 genes).
6. EGL Genetics: Epilepsy and Seizure Disorders (107 genes).
7. NGS Epilepsy/Seizure Panel, Greenwood Genetic Center (145 genes).
8. Courtagen epiSEEK® Comprehensive Sequence Analysis for Epilepsy and Seizure Disorders, Courtagen Life Sciences Inc. (471 genes).
9. Ambry Genetics® EpilepsyNext (100 genes).

Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Code:
0232U - CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions

Original Effective Date: 10/15/2018

Re-Review Date(s): 2/10/2020 – administrative update; format
1/1/2021 – administrative update; code update

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