Confirmatory Genetic Testing

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Description

The Centers for Medicare and Medicaid Services (CMS) developed the Clinical Laboratory Amendments (CLIA) in order to help regulate laboratory tests. CMS intended to use this program as a way to ensure that quality laboratory testing was performed. Laboratories that receive reimbursement from Medicare or Medicaid must be CLIA certified.[1]

Most genetic or genomic tests are performed in a CLIA certified laboratory and used for a clear medical purpose. However, some genetic or genomic tests are performed in a research laboratory that is not CLIA certified or as part of a direct to consumer test that is not necessarily performed for a medical purpose.

When genetic testing is performed in a research laboratory or in a laboratory that is not CLIA certified, it is important to confirm any genetic change found prior to using this information to change an individual's medical treatment.

Criteria

Confirmatory single site genetic testing in a CLIA certified laboratory is medically necessary when the following criteria are met:

- A disease-causing genetic mutation was identified by a laboratory that is not CLIA certified (e.g. research lab), AND
- Healthcare providers can use the test results to directly impact medical care for the individual (e.g. change in surveillance or treatment plan)

Exclusions

- Confirmatory genetic testing is not considered medically necessary if the original testing was performed in a CLIA certified laboratory.
- Confirmatory genetic testing is not considered medically necessary if healthcare providers cannot use the test results to directly impact medical care for the individual.
- Confirmatory genetic testing is not considered medically necessary for variants of unknown significance (VUS).
- Tests that are considered not medically necessary (e.g., APOE for Alzheimer's risk assessment) or experimental, investigational, or unproven (e.g., MTHFR) per eviCore clinical guidelines are not eligible for confirmatory testing.

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References

1. Clinical Laboratory Improvement Amendments (CLIA). CMS.gov website. Available at: https://www.cms.gov/regulations-and-guidance/legislation/clia

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