Medical Necessity Guideline

Medical Necessity Guideline Title: Genetic and Molecular Testing		
MNG #: 02	**☒SCO ☒One Care**	**Prior Authorization Needed? ☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: ☐Yes ☒No	**Approval Date:** 1/10/2019	**Effective Date:** 4/01/2019;
Last Revised Date: 1/25/2019; 02/04/2021	**Next Annual Review Date:** 1/10/2020; 02/04/2022	**Retire Date:**

OVERVIEW:

The purpose of this Medical Necessity Guideline (MNG) is to describe CCA's coverage of medically necessary genetic and molecular diagnostic testing, including next generation sequencing . Genetic testing is used to confirm or rule out a suspected genetic condition that may prove pathological and/or to determine a person's chance of developing or passing on a genetic disorder. Molecular diagnostic testing is used to determine prognosis and/or to predict response to treatment. Genetic and molecular diagnostic testing for the purpose of 'knowing' more without altering the anticipated and available treatment plan is considered not medically necessary and is not a covered service. Next generation sequencing refers to whole genome sequencing which remains resource prohibitive and experimental for almost all indications for personalized medicine.

Prior authorization is required for ALL genetic and molecular diagnostic testing. CCA may use ChangeHealthcare InterQual Molecular Diagnostics criteria when reviewing prior authorization request for coverage when available. This MNG applies to genetic and molecular diagnostic testing without an applicable NCD, LCD, or a test referenced in another MNG including the Experimental and Investigational Services Medical Necessity Guideline (hyperlink). Next generation whole genome sequencing coverage will follow CMS guidelines. See below the list of requirements for all molecular and genetic tests/codes that require prior authorization.

DECISION GUIDELINES:

Clinical Eligibility:

CCA may authorize coverage for specific genetic testing when a member meets ALL the following criteria:

- The member falls within a high-risk group for a particular disease(s) based on personal history, family history, documentation of genetic mutation, and/or ethnic background.
- Patient history, physical examination and conventional diagnostic testing do not result in a definitive diagnosis of a primary disorder.
- The testing method is considered a scientifically proven method for the identification of a specific genetically linked inheritable disease (i.e., the genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of a specific disease, and these observations must be independently replicated and subjected to peer review.)
- For **genetic testing**, CCA requires documentation of counseling by an physician geneticist or a board-certified genetic counselor.
- For **molecular diagnostics**, CCA requires that all requests and documentation must be submitted by a physician with training and expertise in the treatment of the targeted disease.

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- For **next generation whole genome sequencing,** CCA follows CMS guidelines to approve this specific testing only for 1) members with advanced cancer when the testing could guide treatment or for 2) members with any stage of breast or ovarian cancer. This testing may not be approved if this testing has already occurred at any prior time.
- Documentation must include a letter of medical necessity supporting the request for genetic testing, including a review of the current clinical scenario, risk factors, and Member's family history. **This letter, and any supporting documentation (office notes, medical literature if appropriate) must indicate how the results of the genetic test will directly alter the treatment and/or medical management of the Member's diagnosed condition and/or the Member's current pregnancy.**
- Medical necessity letters or genetic testing request forms submitted by the performing lab and signed by the requesting provider will not be accepted as sole documentation.
- InterQual coverage criteria for requested genetic or molecular testing, when available, must be met.

LIMITATIONS/EXCLUSIONS:

- Testing for the purpose of confirming a suspected diagnosis that can be diagnosed by clinical evaluation will not be covered.
- Genetic and molecular diagnostic tests that are scientifically unproven. Refer to CCA MNG Experimental and Investigational Services.
- Testing for conditions which cannot be altered by treatment or prevented with specific interventions are not considered medically necessary and will not be covered.
- Testing solely for the purpose of informing the care of a Member's family member will not be covered, with the exception for prenatal genetic testing.
- Testing must be performed with an in-network laboratory, if available, per the CCA Member Handbook.
- A duplicate test for an inherited condition unless there is documented uncertainty regarding the validity of the prior test result.
- For testing panels, including but not limited to, multiple genes and/or multiple conditions, testing will be covered only for those genes or tests that are reasonable and necessary in order to obtain necessary information for therapeutic decision making and not the entire panel.

KEY CARE PLANNING CONSIDERATIONS:

N/A

AUTHORIZATION:

N/A

REGULATORY NOTES:

N/A

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RELATED REFERENCES:

N/A

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

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