Medical Necessity Guideline

<table>
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<tr>
<th>Medical Necessity Guideline Title: Genetic and Molecular Testing</th>
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<td>MNG #: 02</td>
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<td>Clinical: ☒</td>
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<tr>
<td>Medicare Benefit: ☐ Yes ☐ No</td>
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<td>Last Revised Date: 1/25/2019;</td>
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OVERVIEW:
The purpose of this Medical Necessity Guideline (MNG) is to describe CCA’s coverage of medically necessary genetic and molecular diagnostic testing. 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. Prior authorization is required for all genetic and molecular diagnostic testing. See the listing for tests/codes that require prior authorization below. Refer to the Experimental, Investigational and Unproven Services Medical Necessity Guideline for generic tests which are considered investigational and therefore not covered.

DECISION GUIDELINES:
Clinical Eligibility:
CCA may authorize coverage for specific generic testing, for a Member, when the Member meets ALL of 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 suspecting 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 the observations must be independently replicated and subject to peer review.)
- For genetic testing, documentation of counseling by an MD geneticist or a board-certified genetic counselor is required.
- Documentation must include a letter of medical necessity supporting the request for genetic testing, including a review of 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.
- If applicable, InterQual coverage criteria for requested genetic test must be met.
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Molecular Diagnostics:

- Requests and documentation for molecular diagnostics can be submitted by an MD with expertise in treatment of the targeted disease.
- 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 the observations must be independently replicated and subject to peer review.)
- Documentation must include a letter of medical necessity supporting the request for genetic/molecular testing, including a review of 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.
- 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.

Determination of need:

LIMITATIONS/EXCLUSIONS:
N/A

KEY CARE PLANNING CONSIDERATIONS:
N/A

AUTHORIZATION:
N/A

REGULATORY NOTES:
N/A

RELATED REFERENCES:
N/A

ATTACHMENTS:

| EXHIBIT A: |
| EXHIBIT B |

REVISION LOG:
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APPROVALS:

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