

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to the Medicare Coverage Database for coverage.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Procedure: Genetic Testing

II. Specialties: Primary Care, Pediatrics, Obstetrics and Gynecology, Clinical Genetics

III. Coverage and Limitations

- **A.** KPMAS considers genetic testing to be medically necessary to establish a molecular diagnosis of an inheritable disease when **ALL** of the following are met:
 - 1. The member displays clinical features, or is at direct risk of inheriting the mutation in question (pre-symptomatic); **AND**
 - 2. The result of the test will directly impact the treatment or management being provided for the member; AND
 - **3.** There is a clinically valid genetic test available supported by published peer reviewed literature; **AND**
 - **4.** Tests are limited to the number of genes and test types deemed medically necessary to establish a diagnosis.
- **B.** Preconception Genetic Testing for Kaiser members who are of childbearing age (females aged 9-64 years and males aged 15-123 years) is a covered benefit once a lifetime only for the following conditions:
- 1. Spinal Muscular Atrophy
- 2. Cystic Fibrosis
- 3. Hemoglobinopathies
- **C.** The following limitations apply to genetic testing for members and their genetically related relatives:



1. In the absence of specific information regarding advances in the knowledge of mutation characteristics for a particular disorder, the current literature indicates that genetic tests for inherited disease need only be conducted *once per lifetime* of the member.

2. All individuals undergoing genetic testing for any reason should have both pre- and posttest genetic counseling with a physician or a licensed or certified genetic counselor.

3. We exclude genetic testing of KPMAS members from coverage under KPMAS benefit plans if the testing is performed primarily for the medical management of other family members who are not covered under a KPMAS benefit plan. In these circumstances, the insurance carrier for the non KPMAS family members should be contacted regarding coverage of genetic testing.

4. Occasionally, genetic testing of tissue samples from other family members who are not KPMAS members may be required to provide the medical information necessary for the proper medical care of a KPMAS member. KPMAS covers genetic testing including pre and post testing genetic counseling, for heritable disorders in non-KPMAS members when *all* the following conditions are met:

- **a.** The information is needed to adequately assess risk in the KPMAS member; **AND**
- **b.** The information will be used in the immediate care plan of the KPMAS member; **AND**
- **c.** The non-KPMAS member's benefit plan, if any, will not cover the test (a copy of the denial letter from the non-KPMAS member's benefit plan must be provided).
- 5. Preconception Genetic testing is limited only to Kaiser members.

IV. Diagnoses

- A. After history, physical examination, pedigree analysis, pretest genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain; or
- B. The specific test meets the criteria of current edition of MCG;
- C. After pretest genetic counseling is completed, the genetic counselor or genetic specialist recommend specific tests that meet the criteria of current edition of MCG;
- D. The test is required for BRCA testing or colon cancer treatment, per National Comprehensive Cancer Network (NCCN) guidelines.

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Approval History

Date approved by	Date filed with the State of Maryland	Effective Date
RUMC*		(Ten days after filing)
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Approval History

Effective June 01, 2016, state filing no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC*	Date of Implementation
02/27/2017	02/27/2017
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01/20/2021	01/20/2021
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01/22/2025	01/22/2025

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

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