



---

**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.** 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 post-test 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. KPMAS does not cover genetic testing for heritable disorders in the general population because such screening is of unproven benefit.

#### **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.

#### **References**


1. Brett GR. An exploration of genetic health professionals' experience with direct-to-consumer genetic testing in their clinical practice. - *Eur J Hum Genet* – Aug 2012; 20(8): 825-30.
2. Burke W. Genetic screening.- *Epidemiol Rev* Jan 2011; 33(1): 148-64.
3. Collier R. The downside of genetic screening. - *CMAJ* – May 2010; 184(8): 862-4.
4. Costain G, McDonald-McGinn DM, Bassett AS. Prenatal Genetic Testing with Chromosomal Microarray Analysis Identifies Major Risk Variants for Schizophrenia and Other Later-Onset Disorders. *Am J of Psychiatry*, Dec 2013. 170(12), p. 1498
5. Deo RC. Clinical screening and genetic testing. - *Heart Fail Clin* Apr 2010; 6(2): 231-8.
6. Forrest L. An audit of clinical service examining the uptake of genetic testing by at-risk family members. - *Genet Med* – Jan 2012; 14(1): 122-8.
7. Giardiello FM, Allen JI, Axilbund JE, et al. [Guidelines on genetic evaluation and management of Lynch syndrome: A consensus statement by the U.S. Multi-Society Task Force on Colorectal Cancer](#). American Society for Gastrointestinal Endoscopy, American Gastroenterological Association, American College of Gastroenterology, and the American Society of Colon and Rectal Surgeons. Aug 2014: (80); 2; 197-220.
8. Kaiser Permanente Interregional New Technologies Committee, "Genetic Testing." [https://clm.kp.org/wps/portal/cl/MAS/search\\_iframe?query=INTC](https://clm.kp.org/wps/portal/cl/MAS/search_iframe?query=INTC) . accessed December 28, 2017 multiple tests.



9. Medicare Coverage Database, "[Genomic Testing.](#)" Defer to MEDAC advisory. Accessed 2/10/2016.
10. Meiri E, et al. A second-generation microRNA-based assay for diagnosing tumor tissue origin. *Oncologist* 2012;17(6):801-12.
11. Moyer VA on behalf of US Preventive Task Force (USPSTF). Risk assessment, genetic counseling and genetic testing for BRCA related cancer in women: US Preventive Services Task Force Recommendation statement. *Ann Intern Med.* 2014;160(4):271-281.
12. [National Comprehensive Cancer Network](#). NCCN Clinical Practice Guidelines in Oncology. Accessed Jan 22, 2017.
13. Sijmons RH. A clinical perspective on ethical issues in genetic testing. - *Account Res* May 2011; 18(3): 148-62.
14. Genetic Disorders PDF not available through ClinicalKey [Vinay Kumar MBBS, MD, FRCPath](#), [Abul K. Abbas MBBS](#) and [Jon C. Aster MD, PhD](#), [Robbins and Cotran Pathologic Basis of Disease](#), Chapter 5, 137-183.
15. Regulatory controls for direct-to-consumer genetic tests: a case study on how the FDA exercised its authority. *Margaret. New Genetics & society.* Sept2017, vol.36 Issue 3, p209-226. 18 p. DOI: 10.1080/14636778.2017.1354690.
16. Genetic Testing for Cardiomyopathies in Clinical Practice by Ingles, Jodie; Bagnall, Richard D; Semsarian, Christopher. In *Clinical and Molecular Aspects of Cardiomyopathies: On the Road from Gene to Therapy, Heart Failure Clinics.* April 2018 14(2): 129-137 Language: English. DOI: 10.1016/j.hfc.2017.12.001.
17. Position paper: Genetic counseling and testing of susceptibility genes for therapeutic decision-making in breast cancer – a European consensus statement and expert recommendations by Singer, Christian F; Balmana, Judith; Burki, Nicole; Delalogue, Suzette; Filieri, Maria Elisabetta; Gerdes, Anna-Marie; Grindedal, Eli Marie; Han, Sileni; Johansson, Oskar; Kaufman, Bella; Krajc, Mateja; Loman, Niklas; Olah, Edith; Paluch-Shimon, Shani; Plavetic, Natalia Dedic; Pohlodek, Kamil; rhiem, Kerstin; Teixeira, Manuel; Evans, D. Gareth in *European Journal of Cancer.* January 2019 106:54-60 Language: English DOI: 10.1016/j.ejca.2018.10.007.
18. Genetic testing: covered or not? Critical considerations. Authors: [APPOLD, KAREN](#). Source: [Managed Healthcare Executive](#). Sep2017, Vol. 27 Issue 9, p8-9. 2p.
19. Thiebes, S., Toussaint, P. A., Ju, J., Ahn, J. H., Lyytinen, K., & Sunyaev, A. (2020). Valuable Genomes: Taxonomy and Archetypes of Business Models in Direct-to-Consumer Genetic Testing. *Journal of medical Internet research*, 22(1), e14890. <https://doi.org/10.2196/14890>
20. Ontario Health (Quality) (2020). Genome-Wide Sequencing for Unexplained Developmental Disabilities or Multiple Congenital Anomalies: A Health Technology Assessment. *Ontario health technology assessment series*, 20(11), 1–178.
21. Bordet, C., Brice, S., Maupain, C., Gandjbakhch, E., Isidor, B., Palmyre, A., Moerman, A., Toutain, A., Akloul, L., Brehin, A. C., Sawka, C., Rooryck-Thambo, C., Schaefer, E., Nguyen, K., Dupin Deguine, D., Rouzier, C., Billy, G., Séné, K., Denjoy, I., Leheup, B., ... Charron, P. (2020). Psychosocial Impact of Predictive Genetic Testing in Hereditary Heart Diseases: The PREDICT Study. *Journal of clinical medicine*, 9(5), 1365. <https://doi.org/10.3390/jcm9051365>
22. Katapodi, M. C., Ming, C., Northouse, L. L., Duffy, S. A., Duquette, D., Mendelsohn-Victor, K. E., Milliron, K. J., Merajver, S. D., Dinov, I. D., & Janz, N. K. (2020). Genetic Testing and Surveillance of



- Young Breast Cancer Survivors and Blood Relatives: A Cluster Randomized Trial. *Cancers*, 12(9), 2526. <https://doi.org/10.3390/cancers12092526>
23. Mazzarotto, F., Olivotto, I., Boschi, B., Girolami, F., Poggese, C., Barton, P., & Walsh, R. (2020). Contemporary Insights Into the Genetics of Hypertrophic Cardiomyopathy: Toward a New Era in Clinical Testing?. *Journal of the American Heart Association*, 9(8), e015473. <https://doi.org/10.1161/JAHA.119.015473>
  24. Hendricks-Sturup, R. M., Clark-LoCascio, J., & Lu, C. Y. (2020). A Global Review on the Utility of Genetic Testing for Familial Hypercholesterolemia. *Journal of personalized medicine*, 10(2), 23. <https://doi.org/10.3390/jpm10020023>
  25. American College of Medical Genetics and Genomics (ACMG). ACMG Practice Guidelines. Exome and genome sequencing for pediatric patients , with congenital anomalies or intellectual disability: an evidence based clinical guideline of the American College of Medical Genetics and Genomics (ACMG) Accessed 11/02/2021. <https://www.acmg.net/>
  26. Pierpont, M et al Genetic Basis for Congenital Heart Disease: Revisited: A Scientific Statement From the American Heart Association. *Circulation*. November 20, 2018. Vol 138, Issue 21. 2018;138:e653–e711. Accessed 11/02/2021. <https://www.ahajournals.org/doi/10.1161/CIR.0000000000000606>
  27. Centers for Medicare & Medicaid Services (CMS). National coverage determination (NCD) for next-generation sequencing (NGS) (90.2). <https://www.cms.gov>. Published November 13, 2020. Accessed November 2, 2021. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=372>
  28. Zimmermann, B. M., Shaw, D. M., Elger, B., & Koné, I. (2021). The use of heuristics in genetic testing decision-making: A qualitative interview study. *PloS one*, 16(11), e0260597. <https://doi.org/10.1371/journal.pone.0260597>
  29. ACMG Board of Directors. Clinical utility of genetic and genomic services: a position statement of the American College of Medical Genetics and Genomics. *Genet Med*. Jun 2015;17(6):505-507. PMID 25764213 <https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/2001657.pdf>
  30. Whitehead N, Kahwati L, Meleth S, et al. Genomic microarray and whole exome sequencing. Final Evidence Report. Prepared by the RTI International Evidence-based Practice Center for the Washington State Health Care Authority Health Technology Assessment Program. Olympia, WA: Washington State Health Care Authority; December 19, 2017.
  31. Giuliano, R., Maione, A., Vallefucio, A., Sorrentino, U., & Zuccarello, D. (2023). Preimplantation Genetic Testing for Genetic Diseases: Limits and Review of Current Literature. *Genes*, 14(11), 2095. <https://doi.org/10.3390/genes14112095>
  32. Durbin, M. D., Fairman, K., Helvaty, L. R., Huang, M., Li, M., Abreu, D., Geddes, G. C., Helm, B. M., Landis, B. J., McEntire, A., Mitchell, D. K., & Ware, S. M. (2023). Genetic Testing Guidelines Impact Care in Newborns with Congenital Heart Defects. *The Journal of pediatrics*, 260, 113495. <https://doi.org/10.1016/j.jpeds.2023.113495>

 <b>KAISER PERMANENTE</b> <sup>®</sup> Mid-Atlantic States	<b>Genetic Testing</b>  <b>Medical Coverage Policy</b>
--	--

**Approval History**

<b>Date approved by RUMC*</b>	<b>Date filed with the State of Maryland</b>	<b>Effective Date (Ten days after filing)</b>
01/24/2011	01/24/2011	02/04/2011
01/30/2012	02/02/2012	02/13/2012
01/31/2013	01/31/2013	02/11/2013
01/30/2014	01/31/2014	02/10/2014
02/25/2015	02/27/2015	03/10/2015
02/25/2016	02/29/2016	03/11//2016

**Approval History**

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

<b>Date approved by RUMC*</b>	<b>Date of Implementation</b>
02/27/2017	02/27/2017
02/28/2018	02/28/2018
01/29/2019	01/29/2019
01/14/2020	01/14/2020
01/20/2021	01/20/2021
01/24/2022	01/24/2022
01/24/2024	01/24/2024

\*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.

©2024, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.  
 ©2024, Mid-Atlantic Permanente Medical Group, P.C.