PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY / PROCEDURE

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<tr><td colspan="3">Policy/Procedure Number: MCUP3131</td><td colspan="4">Lead Department: Health Services</td></tr>
<tr><td colspan="3">Policy/Procedure Title: Genetic Screening and Diagnostics</td><td colspan="4">☒ External Policy
☐ Internal Policy</td></tr>
<tr><td colspan="3">Original Date: 08/19/2015</td><td colspan="4">Next Review Date: 01/08/2026
Last Review Date: 01/08/2025</td></tr>
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<tr><td rowspan="2">Reviewing Entities:</td><td colspan="2">☒ IQI</td><td colspan="2">☐ P & T</td><td colspan="2">☒ QUAC</td></tr>
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<tr><td>☐ CEO</td><td>☐ COO</td><td colspan="2">☐ CREDENTIALING</td><td colspan="2">☐ DEPT. DIRECTOR/OFFICER</td></tr>
<tr><td colspan="4">Approval Signature: Robert Moore, MD, MPH, MBA</td><td colspan="3">Approval Date: 01/08/2025</td></tr>
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I. RELATED POLICIES:
MCUP3041 – Treatment Authorization Request (TAR) Review Process

II. IMPACTED DEPTS:
A. Health Services
B. Claims
C. Member Services

III. DEFINITIONS:
A. Biomarker Test: A diagnostic test, single or multigene, of an individual's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide treatment.
B. Medical Necessity: Reasonable and necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury.
C. Multianalyte Assays with Algorithmic Analyses (MAAA): Procedures that utilize multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid-based assays (for example, proteins, polypeptides, lipids, carbohydrates).
D. Proprietary Lab Analyses (PLA): A range of proprietary laboratory services and tests which may include, but is not limited to, multianalyte assays with algorithmic analyses (MAAA) and genomic sequencing procedures (GSP).

IV. ATTACHMENTS:
A. Genetic Testing Requirements
B. Family History Screening Tool
C. Proprietary Laboratory Analyses (PLA) Requirements

V. PURPOSE:
To provide criteria for medical necessity and benefit coverage of genetic testing. Genetic testing is a rapidly expanding aspect of medical care which can be useful for diagnosing disease, guiding treatment, and/or identifying possible genetic risks for development of disease. Given the rapid evolution of this field, it is impossible to establish guidelines to reliably inform when genetic testing is appropriate which will remain valid for a significant time frame. Therefore, the purpose of this policy is to describe the criteria for evaluating requests for genetic testing, and to cite the external professional resources on which we will rely to make coverage determination.

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VI. POLICY / PROCEDURE:

A. Genetic testing generally aims to achieve one of the following goals:
   1. Confirm the diagnosis of a genetic disease
   2. Identify genetic factors which significantly increase an individual's risk for developing a disease
   3. Determine whether a high-risk couple's genetic makeup increases the risk of their children having a genetic disease
   4. Help determine prognosis, effectiveness of various treatment options, and guide management of appropriate diseases
   5. Prenatal or newborn genetic testing to identify diseases in high-risk situations

B. Partnership HealthPlan of California's intent is to follow National Comprehensive Cancer Network (NCCN) guidelines. Decisions about which genetic tests to approve will rely on the most up-to-date recommendations provided by the Centers for Disease Control and Prevention, the National Comprehensive Cancer Network, and the American College of Medical Genetics and Genomics. See Section VII. for URLs for these guidelines.

C. A Treatment Authorization Request (TAR) is required for certain genetic testing as outlined in Attachments A and C. Please note Partnership requirements may differ from California Department of Health Care Services (DHCS) Requirements. Please use Partnership's grids entitled Genetic Testing Requirements (Attachment A) and Proprietary Laboratory Analyses (PLA) Requirements (Attachment C) for Partnership members.
   1. When a TAR is required, medical necessity will be determined upon TAR submission and the following factors will be considered for genetic testing requests:
      a. A definitive diagnosis cannot be made without performing the genetic test being requested AND the results of the genetic testing will influence the treatment or medical management of the patient.
      b. There are identifiable reasons to perform the genetic tests being requested, including a relevant family history or the presence of a clinical condition which suggests a genetic component is relevant to diagnosis or management.
      c. Genetic testing is needed to help guide family planning decisions.
      d. The accuracy of the test has been established, with low proportions of false positive and false negative results.
      e. If a common single gene test is likely to be the cause of the genetic issue in question, a multi-gene test will not be approved until after the single gene test result is negative.
         1) Multi-gene testing may be considered for those who have tested negative (or indeterminate) for one particular syndrome but whose personal and family history is suggestive of an inherited susceptibility.
         2) Multi-gene testing may be considered in cases where more than one pathogenic or likely pathogenic variant could influence a condition.
         3) Clinical documentation indicating clinical impact of the testing that supports medical necessity will be required.
      f. In performing genetic testing of parents to determine risk of an autosomal recessive disease in their offspring, one parent will be tested initially. The other parent will only be tested if the first parent's test indicates the genetic abnormality is present.
      g. The test will be ordered by a clinician who has familiarity with the genetic testing being requested and who has the appropriate expertise to understand the implications of the test and how to follow-up the results.
      h. Testing for any specific gene mutation will only be approved once for the lifetime of any individual person except with a valid TAR override.
      i. Non-disease specific gene panel testing will not be approved (e.g. ancestral testing).

j. Testing solely for the purposes of determining paternity or familial relationships will not be approved.
k. Genetic testing needed for forensic purposes is not covered.
l. Genetic testing will not be approved if the results or outcome may pose a harm to the individual.
m. Genetic testing will not be approved if the only purpose for ordering the testing is one of the following:
   1) As part of a research project
   2) For general screening purposes where there are no high-risk factors indicating that genetic testing may be useful
n. Where the results of the genetic testing have no therapeutic or medical management implications: If expert guidance is not available to validate the appropriateness of a particular genetic test, Partnership reserves the right to request the patient see a geneticist prior to approving the test.

2. In accordance with state law, effective July 1, 2022, no prior authorization is required for medically necessary cancer biomarker testing for members diagnosed with, or being monitored for progression or recurrence of, advanced or metastatic stage 3 or 4 cancer when the treatment is associated with an FDA-approved cancer therapy.
   a. No prior authorization is required, however, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.
   b. Partnership may still require prior authorization for biomarker testing for such members if the biomarker test is not associated with an FDA-approved cancer therapy.
   c. In a prepayment review of each claim, Partnership's Chief Medical Officer or Physician Designee will access the FDA's approved drug database at https://www.accessdata.fda.gov/scripts/cder/daf/ to verify that the treatment plan includes documentation of an agent that is an FDA-approved treatment in the setting of advanced or recurrent cancer and for which the biomarker test (for which the claim is submitted) is medically necessary to determine treatment options.
3. Rapid Whole Genome Sequencing (rWGS) is a covered benefit for any member who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit (ICU).
   a. This includes individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing.
   b. rWGS is an emerging method of diagnosing conditions in time to affect ICU care of children one year of age or younger. rWGS is not a benefit for other ages or settings.
   b. No prior authorization is required, however, a prepayment review after the service has been provided may review the submitted documents to ensure that the documentation reflects medical necessity.

D. Certain genetic tests are not covered by Partnership, however, if ordered by a medical geneticist with appropriate supporting documents attached to the TAR, the request will be considered on an individual basis.
E. For Hereditary Cancer Testing, it is recommended that the provider complete a Family History Screening Tool (Attachment B).
F. For genetic tests related to pregnancy and newborns, please refer to Medi-Cal guidelines in the Genetic Counseling and Screening section *gene coun* 1 – 8.

VII. REFERENCES:

A. Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/genomics-and-health/about/genetic-counseling.html
B. National Comprehensive Cancer Network (NCCN): NCCN Guidelines for Treatment by Cancer Type
C. American College of Medical Genetics and Genomics (ACMG) guidelines: Genetics in Medicine
D. Medi-Cal Provider Manual/ Guidelines: Pathology: Molecular Pathology (*path molec*), Genetic

Counseling and Screening *(gene coun)* and Proprietary Laboratory Analyses (PLA) *(prop lab)*

E. Lynch Syndrome PREMM5 Model: Prediction Model for MLH1, MSH2, MSH6, PMS2, and EPCAM Gene Mutations: http://premm.dfci.harvard.edu/ Kastrinos F, Uno H, Alvero C, McFarland A, Yurgelun MB, Kulke MH, Schrag D, Meyerhardt JA, Fuchs CS, Mayer RJ, Ng K, Steyerberg EW, Syngal S. Development and Validation of the PREMM5 Model for Comprehensive Risk Assessment of Lynch Syndrome. Journal of Clinical Oncology. 2017 Jul 1;35(19):2165-2172. doi: 10.1200/JCO.2016.69.6120. Epub 2017 May 10.
F. Department of Health Care Services (DHCS) All Plan Letter (APL) 22-010 Cancer Biomarker Testing (06/22/2022)
G. Assembly Bill (AB) 133, 2021-2022 Regular Session, Rapid Whole Genome Sequencing
H. California Department of Public Health (CDPH) California Genetic Disease Screening Program (GDSP) https://sis2-prod.powerappsportals.us/homepage/

VIII. DISTRIBUTION:
A. Partnership Department Directors
B. Partnership Provider Manual

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Chief Health Services Director

X. REVISION DATES:
8/19/15; 11/18/15; 06/15/16; 02/15/17; 08/16/17; *05/09/18; 09/12/18; 03/13/19; 08/14/19; 11/13/19; 05/13/20; 08/12/20; 05/12/21; 09/08/21; 10/12/22; 10/11/23; 01/08/25

*Through 2017, Approval Date reflective of the Quality/Utilization Advisory Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO:
MCUP3108 BRCA - Gene Sequence Analysis was archived 08/19/2015

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In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:

- Consistent with sound clinical principles and processes
- Evaluated and updated at least annually
- If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request

The materials provided are guidelines used by Partnership to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership. Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.