IEHP UM Subcommittee Approved Authorization Guideline			
Guideline	Genetic Testing	**Guideline #**	UM_DIA 17
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Section	Diagnostic Testing	**Revision Date**	N/A
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COVERAGE POLICY

Genetic testing is the analysis of DNA, RNA, or proteins to identify changes in molecular sequence or expression levels. This is done to identify deviations in the structure of these molecules which may prove useful in diagnosing disease, guiding treatment, and/or identifying risks for the development of disease. Genetic testing is a rapidly expanding aspect of medical care. According to the National Institutes of Health, as of November 2022, there were more than 76,000 different genetic tests offered worldwide, with over 37,000 available in the United States alone. Therefore, developing guidelines to determine medical necessity for every one of these assays would not be possible. However, IEHP has endeavored to develop a framework to assist in the review of these requests. A literature review of clinical studies, scientific journals and other peer-worthy publications has shown that genetic testing is performed for one of the following indications:

- To confirm the diagnosis of a genetic disease
- To identify genetic factors which significantly increase an individual's risk for developing a disease
- To determine whether a high-risk couple's genetic makeup increases the risk of their children having a genetic disease
- To help determine prognosis, effectiveness of various treatment options, and guide management of appropriate diseases
- To identify diseases in high-risk situations in fetal or newborn Members

The following will be IEHP's process for reviewing requests for genetic testing:

1. If a Medi-Cal Member, determine whether a Treatment Authorization Request (TAR) is required (e.g. a test is referenced in the Medi-Cal Provider Manual [MCPM]).
    a. If approved (based on the process below) testing for any specific gene mutation will be allowed only once during the lifetime of a Member, except in the case of a Medi-Cal Member with a valid TAR override.
2. Verify that genetic testing has a labeled indication that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.
3. If a Medicare Member, determine if a genetic test has a Local Coverage Determination (LCD), Local Coverage Article (LCA), National Coverage Determination (NCD), or

Medicare Benefit Policy Manual (MBPM) citation for it. If so, use this to review your request against.

4. For Hereditary Cancer Testing, it is recommended that the Provider complete a Family History Screening Tool. Please see Attachment A.
5. For genetic testing related to pregnancy and newborn(s) of a Medi-Cal Member, please refer to the MCPM guidelines in the Genetic Counseling and Screening section.
6. Requested genetic testing is to be reviewed against nationally recognized clinical criteria listed in IEHP policy (14A Utilization Management – Delegation and Monitoring) to determine the medical appropriateness of health care services. This criteria is supported by evidence-based clinical practice guidelines, supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff[1].
7. The determination of medical necessity is made according to line of business. Factors in determining medical necessity are the following-
    a. Genetic testing will be required to make a definitive diagnosis, AND the results of the genetic testing will influence the future treatment or medical management of the Member.
    b. Reasons have been identified justifying the performance of said testing (family history of a disease, signs or symptoms suggestive of a genetic disease, etc.).
    c. Results of genetic testing are required to help guide family planning decisions.
    d. When a single gene test is likely to identify the cause of a suspected genetic disease, a multi-gene panel will not be approved until after the single gene test result is negative. More specifically clinical documentation must show that:
        i. A Member has tested negative or indeterminate for one particular gene but who's personal and/or family history is suggestive of an inherited genetic syndrome.
        ii. More than one gene could be suspected of causing a disease.
    e. When genetic testing is done to determine a parent's risk of passing on an autosomal recessive disease to their offspring, one parent will be tested initially. The other parent will only be tested if the first parent's test result is positive.
    f. Genetic testing must be ordered by a Provider who has familiarity with the genetic disease and corresponding diagnostic test in question. This is because the ordering Provider must understand the implications of the test and how it will influence Member's subsequent medical care.
    g. Testing for any specific gene mutation will be approved only once during the lifetime of a Member.

COVERAGE LIMITATIONS AND EXCLUSIONS

1. Non-disease specific gene panel testing will not be approved (e.g. direct to consumer genetic testing where a clinician's order is not required- ancestral testing, etc.).
2. Testing solely for the purpose of determining paternity or familial relationships will not be approved.
3. Genetic testing needed for forensic purposes is not covered.
4. Genetic testing will not be approved if the results or outcome pose harm to the individual.
5. Genetic testing will not be approved if the only purpose for ordering the testing is one of the following:

[1] Standards set by the National Academy of Medicine.

a. As part of a research project.
b. For general screening purposes where there are no high-risk factors indicating that genetic testing will be useful.

6. Genetic testing will not be approved if the results have no therapeutic or medical management value. If expert guidance is not available to validate the appropriateness of a particular genetic test, IEHP reserves the right to request the patient see a geneticist prior to referral adjudication.

ADDITIONAL INFORMATION

1. In accordance with state law, as of July 01, 2022, no prior authorization is required for medically necessary cancer biomarker testing for Members diagnosed with, or who are 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. IEHP may still require prior authorization for biomarker testing for such Members if the biomarker test is not associated with an FDA-approved cancer therapy.
2. In accordance with state law (AB-133), IEHP covers Rapid Whole Genome Sequencing (rWGS), including individual sequencing, trio sequencing for a parent or parents and their baby and ultra-rapid sequencing. rWGS is a covered benefit for any Medi-Cal member who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit. However, if Member is eligible for California Children's Services (CCS), CCS may be responsible for covering the hospital stay and the rWGS.
    a. No prior authorization is required, however, a prepayment review after the service has been provided may review the submitted documents to ensure the medical necessity threshold has been met.

CLINICAL/REGULATORY RESOURCE

1. The Knox-Keene Health Care Service Plan Act of 1975, California Health and Safety Code, Chapter 2.2, section 1340 et seq., and Title 28, 2025 edition.
2. California Senate Bill 496, Biomarker Testing, passed 2023-10-07 – Chaptered by Secretary of State. Chapter 401, Statutes of 2023.
3. California Senate Bill 535, Biomarker Testing, passed 2021-10-06 – Chaptered by Secretary of State. Chapter 605, Statutes of 2021.
4. 2024 California Health and Safety Code – HSC Division 2 – Licensing Provisions Chapter 2.2 – Health Care Service Plans Article 5- Standards Section 1367.667.
5. 2024 California Health and Safety Code – HSC Division 2 – Licensing Provisions Chapter 2.2 – Health Care Service Plans Article 5- Standards Section 1367.665.
6. California Assembly Bill 133, Committee on Budget. Health. Section on the Whole Genome Sequencing Pilot Project.

DEFINITION OF TERMS

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, to guide treatment.

DNA – a molecule that carries the genetic instructions for all living organisms.

Next Generation Sequencing – is a broad term used to describe technologies that enable high-throughput DNA sequencing by processing fragments in parallel. Rapid Whole Genome Sequencing (please see below) is a type of Next Generation Sequencing.

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).

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).

Protein – the building blocks of the body, playing a crucial role in growth, repair, and various bodily functions.

Rapid Whole Genome Sequencing (rWGS) – a technology that allows for quick analysis of a individual's entire genome to identify genetic causes of illness. It involves extracting DNA from a patient, sequencing it, and then comparing it to reference standards to identify potential genetic mutations. The process may be completed in less than 24 hours.

RNA – a molecule carrying genetic information from DNA that is translated into proteins by the machinery of the cell.

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DISCLAIMER

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