	POLICIES AND PROCEDURES
Policy #: 404-1715	Lead Department: Utilization Management
Title: Genetic Testing	
Original Date: 03/12/2016	Date Published: 12/13/2024
Approved by: Utilization Management Work Group (UMWG)	

Purpose:

To facilitate the process for approval of genetic testing for Alliance members.

Policy:

Central California Alliance for Health (the Alliance) will provide evidence-based testing for genetic disorders and syndromes, genetic mutations that may predispose members to cancer or other disease, genetic susceptibility to adverse drug events, and tumor genetic mutation and expression profiles in order to better guide cancer treatment.

The Alliance covers all medically necessary biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a condition, including:

- FDA-approved testing
- National coverage determination by CMS
- Local coverage determination by Medicare Administrative Contractor for CA
- Evidence-based clinical practice guidelines
- Standards set by the National Academy of Medicine


The Alliance ensures biomarker testing is authorized in a manner that limits disruptions in care.

Definitions:

Array-based Comparative Genomic Hybridization (CGH): A high resolution karyotype hybridizing labeled DNA from the patient to a set of chromosomes from a control patient with no duplications or deletions of DNA. Excess DNA in a specific region compared with the control signifies a duplication of genes in that region. Decreased DNA signal in comparison to the control signifies a deletion of genes from that region. If a duplication or deletion is present in a specific region, follow up testing may be indicated if there is a known gene in this region that could explain the patient's clinical abnormality (e.g. developmental delay).

Biomarker: a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a specific therapeutic intervention. A biomarker includes, but is not limited to, gene mutations or protein expression.

Biomarker test: the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests, and whole genome sequencing.ⁱ

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California Children's Services (CCS): CCS is a state program for children with certain diseases or health problems. Through this program, children up to 21 years of age can get the health care and services they need for CCS-eligible conditions. CCS also provides medical therapy services that are delivered at public schools through their Medical Therapy Unit (MTU).

Genetic Counseling: Counseling of a patient (pre and post testing) by a physician trained in clinical genetics, a Medical Geneticist, or a certified genetic counselor (Master of Science in genetic counseling), or an Oncologist/Hematologist or Oncologic Surgeon. Family history and the development of a pedigree are often an integral part of this process.

Germline Mutation Testing: Testing for mutations that are inherited and present in every cell of a patient's body- usually a blood test.

Karyotyping: Displaying the chromosomes within a cell so that duplications or deletions of chromosomes, or large parts of a chromosome, can be detected in order to diagnose and plan treatment for a genetic disease or syndrome.

Large/extended gene panel testing: Sequencing/screening for mutations in a very large set of genes – usually 30 to 200 genes.


Pharmacogenetics: Testing for mutations in genes that are involved in drug metabolism. This may be useful in determining if a patient will have an adverse reaction to a prescribed medication.

RNA Expression Testing (e.g. Oncotype Dx): Testing (usually of a tumor) for the expression of RNA from genes that are known to be associated with a specific function such as metastasis.

Single gene/ limited panel testing: Sequencing or screening a single gene/or a small set of genes (usually less than 10) for mutations that diagnose a disease or confer an increased risk of disease.

Tumor testing: Testing a tumor specimen for the presence or absence of specific tumor mutations that may guide selection of chemotherapy, or the expression of specific genes that may determine the need for chemotherapy or radiation.

Whole Child Model (WCM): The purpose of the WCM program is to incorporate services covered by the CCS Program into Medi-Cal managed care for Medi-Cal-eligible CCS Program members. Managed care plans (MCPs) operating in WCM counties will integrate Medi-Cal managed care and CCS Program administrative functions to provide comprehensive treatment of the whole child and care coordination in the areas of primary, specialty, and behavioral health for CCS-eligible and non-CCS-eligible conditions.


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Whole Exome Sequencing (WES): Sequencing/ screening for mutations in all coding regions of the DNA (~1.5% of the genome). ~180,000 exons coding for 22,000 genes are analyzed.

Whole Genome Sequencing (WGS): The entire genome (including exons and intervening DNA) is sequenced.

Procedures:


- 1) In most cases, genetic tests will be referenced with guidelines in Medi-Cal or MCG care guidelines), or both. Many single gene tests and simple karyotype evaluations do not require Medi-Cal approval, and this will be listed in the guidelines.
- 2) The Alliance will provide medically necessary biomarker testing for members with advanced or metastatic stage 3 or 4 cancer; or, biomarker testing for cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.
 - a. The Alliance will not require prior authorization on biomarker testing that is associated with a federal Food and drug Administration (FDA)-approved therapy for advanced or metastatic stage 3 or 4 cancer.
 - b. If the biomarker test is not associated with an FDA-approved cancer therapy for advanced or metastatic stage 3 or 4 cancer, the Alliance may still require prior authorization for such testingⁱⁱ.
 - c. The Alliance will not limit, prohibit, or modify a member's rights to cancer biomarker testing as part of an approved clinical trial, in accordance with HSC Section 1370.6.
 - d. The Alliance periodically reviews the list of cancer biomarker tests that are associated with a federal FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer, to ensure the Alliance identifies any updates to the FDA's drug therapy approvals.
- 3) If the genetic test is not referenced in Medi-Cal then MCG care guidelines will apply.
- 4) If the genetic test is referenced in Medi-Cal guidelines and the patient meets these guidelines, then the test can be approved. The Alliance can offer and recommend genetic counseling but if this is not required by the Medi-Cal guidelines, then the test can be approved without verification of counseling.
- 5) If the genetic test is referenced in Medi-Cal guidelines but the patient does not meet Medi-Cal criteria, MCG care guidelines should be used. If the requested test meets MCG care guidelines

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and genetic counseling is available through the requesting provider's organization, then the testing may be approved.

- 6) If the requested test does not meet Medi-Cal or MCG care guidelines, the request is forwarded to Medical Director for review and determination.
- 7) If the requested test is not referenced by Medi-Cal or MCG care guidelines, then these guidelines do not apply. Locate the requested test on the intended testing lab website for information and save pertinent information as a .pdf for Medical Director review. The request is then forwarded to the Medical Director for review and determination.
- 8) When genetic testing requests are received for WCM CCS members, and the request is related to the CCS eligible condition, CCS policy must be followed. At the present time, that includes CCS Numbered Letters 03-0518, 06-0718 and 08-1011. Testing to identify genetic causes of hearing loss is a benefit. Testing to identify adrenoleukodystrophy is a benefit. In general, genetic testing must be expected to affect the treatment, or prognosis of the CCS eligible condition, or be necessary for the diagnosis of a CCS eligible condition.
 - a. For WCM eligible members, requests for genetic testing shall be considered when:
 - i. Submitted by CCS Program-paneled geneticist, CCS Program physician at an approved SCC, or CCS Program-paneled subspecialist;
 - ii. A request is submitted with documentation that provides compelling justification of medical necessity, specifically that the genetic test result is likely to impact the diagnosis or treatment of the client's CCS Program-eligible condition. Testing for potential incidental findings will not be authorized.
 - iii. A specific genetic test may be authorized only once during the client's enrollment in the CCS Program, unless there is new knowledge of mutations linked to a particular disorder, confirmation that the initial result did not have the required specificity, or verification that the previously authorized genetic test was not completed.
 - iv. Genetic testing can be authorized to a Medi-Cal approved genetic laboratory or to a hospital with an outpatient genetic laboratory. Laboratory testing must be authorized to and performed by a laboratory that is enrolled as a Medi-Cal provider.

Additional Genetic Testing Policy Considerations:

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- 1) Single and small panel gene testing may be appropriate if Medi-Cal or MCG care guidelines are met and/or there is compelling evidence of a genetic mutation from the family history that could affect treatment or screening for the member.
 - a. If the patient's diagnosis is evident from clinical signs and symptoms, or protein testing, then genetic testing is often unnecessary.
 - b. Reflex testing for large rearrangements in genes such as BRCA1/BRCA2 and PTEN are only approved if initial sequencing of these genes is negative for mutations, since these more complex tests are not necessary if a mutation is found in the initial screening test.
- 2) Genetic testing must be able to provide information that would result in correcting or ameliorating defects i.e., change clinical management, or improve care of the member for whom the request was made.
- 3) An Independent Medical Review may be requested by service related to the reason the genetic test is being ordered (autism spectrum disorder, intellectual disability, neurologic deficit, etc.) to further clarify whether the genetic testing will change clinical management or improve care for the member.
- 4) Tumor testing may not be addressed in MCG care guidelines but may nonetheless be evidenced-based and important to the patient's care. National Cancer Care Network (NCCN) Guidelines may be more appropriate for determining medical necessity for tumor testing.³
- 5) Array CGH testing is indicated for unexplained developmental delay, autism spectrum disorder, or intellectual disability only if there is not a diagnosis that is evident from the initial metabolic and clinical evaluation.
- 6) Pharmacogenetic testing is rarely recommended but may be indicated if the patient requires a medication that contains a black box warning from the FDA for persons with specific genetic abnormalities.^{4,5}
- 7) Genetic counseling is covered by Medi-Cal if it is performed by, or under the supervision of a board-certified Medical Geneticist, who has been certified by Medi-Cal. Counseling should be encouraged so that members can fully understand the potential impact of genetic testing and also how genetic test results might (or might not) affect their health and their families.⁶

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- 8) Rapid Whole Genome Sequencing: Rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, 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.

References:

Alliance Policies:

Impacted Departments:

Community Care Coordination

Member Services

Pharmacy

Provider Services

Regulatory:

CCS Numbered Letter 03-0518 Authorization of Genetic Testing – REVISED

CCS Numbered Letter 06-0718 Authorization of Diagnostic and Treatment Service for Infants

Referred by the California Newborn Screening (NBS) Program for X-Linked Adrenoleukodystrophy (ALD)

CCS Numbered Letter 08-1011 Genetics Evaluation for Children with Hearing Loss

DHCS 2022 Evidence of Coverage (EOC) Errata

Legislative:

DMHC APL 21-025: Newly Enacted Statutes Impacting Health Plans

SB 535; Biomarker Testing

Senate Bill (SB) 496 – Biomarker Testing

Contractual (Previous Contract):

Contractual (2024 Contract):


DHCS All Plan Letter:

NCQA:

Supersedes:

Other References:

1. National Library of Medicine: Green RC, Berg JS, Grody WW, Kalia SS, Korf BR, Martin CL, McGuire AL, Nussbaum RL, O'Daniel JM, Ormond KE, et al. ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. Genet Med. 2013 Jul;15(7):565-74. doi: 10.1038/gim.2013.73. Epub 2013 Jun 20. PubMed PMID: 23788249; PubMed Central PMCID: PMC3727274.
2. National Library of Medicine: ACMG Board of Directors. ACMG policy statement: updated recommendations regarding analysis and reporting of secondary findings in clinical genome-scale sequencing. Genet Med. 2015 Jan;17(1):68-9. doi: 10.1038/gim.2014.151. Epub 2014 Nov 13. PubMed PMID: 25356965.

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3. National Comprehensive Cancer Network: Treatment by Cancer Type - http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
4. Wang L, McLeod HL, Weinshilboum RM. Genomics and drug response. N Engl J Med. 2011 Mar 24;364(12):1144-53. doi: 10.1056/NEJMra1010600. Review. PubMed PMID: 21428770; PubMed Central PMCID: PMC3184612.
5. US Food & Drug: Table of Pharmacogenomic Biomarkers in Drug Labeling - <http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm>
6. Medi-Cal Genetic Counseling Guideline: <http://www.medi-cal.ca.gov/serp.asp?q=genetic+counseling&cx=001779225245372747843%3Ajl7cpn-0my4&cof=FORID%3A10&ie=UTF-8>
7. American Academy of Pediatrics: Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays - <https://publications.aap.org/pediatrics/article/134/3/e903/74189/Comprehensive-Evaluation-of-the-Child-With-Developmental-Delays>
Identification, Evaluation, and Management of Children with Autism Spectrum Disorder - <https://publications.aap.org/aapnews/news/7662>
8. National Library of Medicine, National Center for Biotechnology Information: Promoting Optimal Development: Identifying Infants and Young Children with Developmental Disorders Through Developmental Surveillance and Screening <https://pubmed.ncbi.nlm.nih.gov/31843861/>

Attachments:

Lines of Business This Policy Applies To


- ☐ DSNP
☒ Medi-Cal
☒ Alliance Care IHSS

LOB Effective Dates

(01/01/2026 – present)
(01/01/1996 – present)
(07/01/2005 – present)

Revision History:

Reviewed Date	Revised Date	Changes Made By	Approved By
07/08/2022	07/08/2022	Paige Harris, Regulatory Reporting Supervisor	UMWG
03/15/2023	03/15/2023	Tammy Brass, RN UM Director	UMWG
09/15/2023	09/15/2023	Danah Hernandez, UM Regulatory Reporting Supervisor	UMWG
02/07/2024	02/07/2024	Carissa Grepco, RN	UMWG

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		UM Manager – Prior Auth	
11/12/2024	11/12/2024	Tisa Llamas, RN Prior Authorizations Supervisor	UMWG

ⁱ Senate Bill (SB) 496 – Biomarker Testing

ⁱⁱ DHCS APL 22-010 – Cancer Biomarker Testing