



State of California—Health and Human Services Agency Department of Health Care Services



EDMUND G. BROWN JR.
GOVERNOR

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Index: Benefits

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM
ADMINISTRATORS, MEDICAL CONSULTANTS, INTEGRATED
SYSTEMS OF CARE DIVISION STAFF, (ISCD) AND THE
GENETICALLY HANDICAPPED PERSONS PROGRAM (GHPP)

SUBJECT: AUTHORIZATION OF GENETIC TESTING - REVISED

I. PURPOSE

The purpose of this updated Numbered Letter (N.L.) is to update the CCS Program policy regarding the authorization of Genetic testing.

II. BACKGROUND

Pediatric specialists routinely recommend genetic testing for children and young adults with CCS Program-eligible medical conditions, for purposes of diagnosis, optimal treatment, genetic counseling and family planning.

Current state CCS Program policy requires review of the results of specific genetic testing before the authorization of some specialty medication. These medications are approved by the Federal Drug Administration for treatment of conditions with specified genetic mutations.

Current state CCS Program standards for tertiary hospitals and certain SCCs require the inclusion of CCS Program-paneled geneticists and genetic counselors.

III. POLICY

Effective the date of this letter, genetic testing is a CCS Program benefit when:

- A. Prescribed by a CCS Program-paneled subspecialist at a CCS Program-approved SCC, by a CCS Program-paneled clinical or biochemical geneticist, or by a CCS Program-paneled pediatric subspecialist at center type not reviewed by

CCS Program for:

1. A CCS Program/GHPP client whose care is under the supervision and monitoring of a CCS Program-paneled subspecialist, CCS Program-approved SCC, or CCS Program-paneled clinical or biochemical geneticist, or
2. An individual who meets criteria for CCS Program or GHPP, with signs and symptoms, laboratory studies or newborn screening results indicating a high likelihood of a condition.

B. A request is submitted with documentation that provides compelling justification of medical necessity, specifically that the genetic test result is likely to have a significant impact on the diagnosis or treatment of the client's CCS Program-eligible condition. Testing for potential incidental findings will not be authorized.

C. 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.

D. Types of genetic testing that may be authorized when medically necessary for diagnosis or treatment of a CCS eligible condition include, but are not limited to the following:

1. Karyotype;
2. Chromosomal microarray (also known as comparative genomic hybridization);
3. Gene sequencing of individual genes or gene panels;
4. Whole exome sequencing;
5. Exome slice sequencing; and;
6. Chromosomal breakage studies.

The least costly medically necessary test will be authorized unless a more complex test is likely to provide essential findings. For example, a single gene test will be authorized instead of a panel unless multiple tests in a panel are likely to provide information essential for the diagnosis or treatment of the CCS eligible condition.

- E. Genetic testing can be authorized to a Medi-Cal approved genetic laboratory or to a hospital with an outpatient genetic laboratory.
 - 1. Laboratory testing must be authorized to and performed by a laboratory that is enrolled as a Medi-Cal provider.
 - 2. Approved laboratories and hospitals include, but are not limited to:
 - a. Ambry Genetics
 - b. ARUP Laboratories
 - c. Gene Dx
 - d. Fulgent Therapeutics
 - e. Children's Hospital Los Angeles
 - f. University of California, San Francisco
 - g. University of California, Los Angeles
 - h. Stanford University
 - i. City of Hope Medical Foundation
 - 3. To identify genetic laboratories enrolled in the Medi-cal program, users can access the Open Data Portal. The information is based on a point-in-time and generally is updated monthly.
Please see the link to access the Open Data Portal:
<https://data.ca.gov/>
- F. The County CCS Medical Director for independent counties, or State CCS Medical Consultant for dependent counties, shall review the medical documentation submitted by the provider in order to ensure that the requested test is medically necessary and appropriate:

1. To establish the presence of a CCS Program-eligible condition.
2. To optimize treatment of a CCS Program-eligible condition.

G. If the county or state medical consultant determines that the justification submitted is not sufficient, then the requesting CCS Program SCC center will need to submit a request for the test by a geneticist or genetic counselor affiliated with the center.

IV. POLICY IMPLEMENTATION

- A. Requests for medically necessary genetic testing shall be authorized when:
 1. Submitted by CCS Program-paneled geneticist, CCS Program physician at an approved SCC, or CCS Program-paneled subspecialist;
 2. The client meets the criteria in III. A. through III D. above;
 3. The laboratory meets the criteria in III. E. above;
 4. The CPT code is recognized in the PMF; and
 5. If a genetic laboratory, service is deemed medically necessary by the county CCS program Medical Director but its code is not active in the PMF, then the county may authorize code 81479, Unlisted Molecular Pathology Procedure. Claims using this code are paid via invoice and report when authorized by CCS Program.
- B. When the CCS Program-paneled specialist or CCS Program-approved SCC documents that no/ Medi-Cal-enrolled laboratory is available to perform the necessary tests, the CCS Program may encourage the laboratory to enroll as a Medi-Cal provider.

Provider enrollment information for both in-state and out-of-state clinical laboratory providers is available on the Provider Enrollment Division Website: <http://www.dhcs.ca.gov/provgovpart/Pages/PED.aspx>

- C. Exceptions to this policy will be reviewed on a case-by-case basis by ISCD Medical Director or designee.

If you have any questions regarding this N.L., please contact Jill Abramson, M.D., M.P.H., by telephone at (916) 327-2108 or by e-mail at Jill.Abramson@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

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