



STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES


Med-QUEST Division
Health Care Services Branch
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June 22, 2020

MEMORANDUM

MEMO NO.
QI-2021

TO: QUEST Integration (QI) Health Plans

FROM: Judy Mohr Peterson, PhD 
Med-QUEST Division Administrator

SUBJECT: GUIDANCE ON SARS-COV-2 ANTIBODY TESTING

The purpose of this memorandum is to provide guidance regarding SARS-CoV-2 antibody (serology tests) for the COVID-19 disease. In sum, serological antibody testing may be covered if FDA approved when medically necessary.

The Food & Drug Administration (FDA) requires companies producing commercially marketed serology tests to provide standardized information regarding the accuracy of their tests. In short, if the expected performance of a test meets a minimum level of accuracy, it will receive Emergency Use Authorization (EUA). While the FDA has granted 18 tests EUA as of June 19, 2020, they continue to review other tests and the EUA list of tests will continue to be revised. The latest list of tests that have been granted EUA can be found on the FDA website:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>

Hawaii Medicaid may cover SARS-CoV-2 serology tests that have been granted EUA by the FDA and meet the criteria for medical necessity. Serology tests that have not been granted EUA by the FDA are not covered. At this time, examples that meet criteria for medical necessity where serology testing may be covered include but are not limited to the two listed below:

- As a method to support the diagnosis of acute COVID-19 illness for persons who present late with complications of COVID-19 illness such as multisystem inflammatory syndrome in children;
- For persons who present 9-14 days after illness onset, serologic testing can be offered in addition to recommended direct detection methods such as polymerase chain reaction. https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Fclinical-criteria.html

Examples in which serologic testing will NOT be covered include but are not limited to the examples below:

- Recent CMS guidelines are that serologic testing should not be used to determine immune status in individuals until the presence, durability, and duration of immunity is established.
- Serologic test results should not be used to make decisions about grouping persons residing in or being admitted to congregate settings, such as schools, dormitories, or correctional facilities.
- Serologic test results should not be used to make decisions about returning persons to the workplace.
- Serologic testing should not be used as the sole basis for diagnosis of acute infection.

Billing for covered SARS-CoV-2 serology test should use the following CPT codes:

- CPT 86328 – immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single strip method (e.g., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) (coronavirus disease [COVID-19
- CPT 86769 – Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

It is the responsibility of the QI health plan to ensure the billed serology test has been granted EUA by the FDA. Payments may be made for covered serology tests with dates of service on or after April 10, 2020.

Our guidance may be updated as new recommendations are made. Questions regarding this memo can be sent to Jon Fujii at jfujii@dhs.hawaii.gov.