DATE: August 7, 2020

SUBJECT: COVID-19 Virus and Antibody Testing

As the COVID-19 public health emergency continues to evolve, the Department of Health Care Services (DHCS) remains dedicated to closely monitoring and assessing appropriate next steps as well as releasing guidance to ensure the safety of Medi-Cal beneficiaries, health plan enrollees, medical providers, and California communities in general.

COVID-19 Viral and Serologic (Antibody) Testing

DHCS covers both COVID-19 viral and serologic (antibody) tests, at no cost to Medi-Cal beneficiaries. This includes all medically necessary viral and serologic testing as well as serologic (antibody) tests ordered for infection control purposes (e.g. pre-operative screening or planned hospitalizations). We recommend that all Medi-Cal providers follow the testing guidance provided by the California Department of Public Health (CDPH), the Centers for Disease Control and Prevention (CDC), and other governmental and professional organizations with expertise on COVID-19 testing. Below is a summary of some of the key guidance on serologic testing.

The CDPH testing guidance for health care providers states: “Serologic tests should generally not be used to diagnose acute cases of COVID-19 or to infer immunity.” In addition, the American Medical Association (AMA) has developed recommendations for the consideration and use of serologic tests to help guide providers and individuals considering using them. Based on this guidance, DHCS is issuing the following clarifications and policy on the use and coverage of serologic testing in Medi-Cal.

Providers should pay close attention to the regulatory status of any test offered. The Food and Drug Administration (FDA) maintains a listing of all serologic tests authorized for use for COVID-19. Providers should be aware of the performance characteristics of any test used and how those align with the FDA recommended performance standards. Providers should note that there has been reported fraudulent marketing of some tests and should verify the regulatory status of these claims before incorporating them in to practice.

COVID-19 Testing of Beneficiaries in Long Term Care Facilities

Many Medi-Cal beneficiaries reside in long-term care facilities; on July 17, 2020, the CDC released revised guidance for nursing home facilities to follow for testing residents who are at high risk for infection, serious illness, and death from COVID-19. DHCS
encourages all Medi-Cal nursing homes to adhere to the CDC interim guidance, including the Preparing for COVID-19 in Nursing Homes.

**Medi-Cal COVID-19 Tests Procedure and Billing Information**

As new COVID-19 procedure, diagnostic, and laboratory codes are announced by the Centers for Medicare and Medicaid Services, DHCS is proactively updating the billing systems and releasing Newsflashes to ensure providers are able to bill Medi-Cal for COVID-19 tests and medical care. For additional information, including information on COVID-19 testing procedure and billing codes, see the frequently asked questions (FAQs) below and/or visit the Pathology Microbiology Provider Manual website.

**Additional Resources**

Several state and federal agencies have COVID-19 website resources for individuals, health care providers, and laboratories related to virus and antibody testing:

- The California Coronavirus COVID-19 Testing Task Force website provides information on the statewide efforts to expand COVID-19 testing locations and also includes COVID-19 laboratory resources. Medi-Cal providers including laboratories are encouraged to review these websites for additional testing information.

- CDPH recently updated its interim guidance intended to support public health officials, health care providers, and laboratories to prioritize specific groups for testing. Additional information on their sequential expansion of testing is located on this website link, CDPH categorizes priority groups.

- The CMS website includes the April 11, 2020 and June 23, 2020, FAQs about the federal Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act.

- CDCs website contains information on COVID-19 viral and serologic tests and more detailed guidance on serologic tests. Additionally, the CDC website includes guidance to individuals about COVID-19 symptoms and information on when to seek appropriate medical care or COVID-19 testing, and on July 17, 2020, CDC released interim guidance on COVID-19 testing of healthcare personnel.

For additional COVID-19 information and resources, we encourage you to review the following resources:

- covid19.ca.gov/
- DHCS COVID-19 Response
- Latest news from California Department of Public Health (CDPH) about COVID-19 || En Español
- CDPH Testing categories
- U.S. Food & Drug Administration FAQs on Diagnostic Testing for COVID-19
DHCS Frequently Asked Questions

1. **Which COVID-19 tests are covered benefits?**
   Medi-Cal covers all medically necessary FDA approved COVID-19 tests.

2. **Which Medi-Cal beneficiaries are eligible for a COVID-19 test?**
   All enrolled Medi-Cal beneficiaries are eligible for a COVID-19 test, when determined medically necessary. Additionally for all enrolled Medi-Cal individuals, regardless of their scope of coverage, DHCS has deemed COVID-19 testing, testing-related and related medically necessary treatment services, including services rendered outside of hospital emergency department, as an emergency service to treat an emergency medical condition.

3. **When is a COVID-19 test medically necessary?**
   To determine when a COVID-19 test is medically necessary, providers should follow the CDPH COVID-19 testing guidelines for public health officials, healthcare providers, and laboratories. Under Medi-Cal, medical necessity is defined in Section 14059.5 of the Welfare and Institutions Code as follows:
   - For individuals 21 years of age or older, a service is “medically necessary” or a “medical necessity” when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
   - For individuals under 21 years of age, consistent with state and federal laws and regulations for the Early and Periodic Screening, Diagnostic, and Treatment benefit, medically necessary services, include those to “correct or ameliorate” defects and physical and mental illnesses or conditions.

4. **What is the frequency limit on COVID-19 tests?**
   Each code has a frequency limit of two per day, per patient for each code.

5. **Can a practitioner receive payment for specimen collection?**
   Providers can be paid for assessment and specimen collection for COVID-19 testing using CPT 99211.

6. **Can the Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) visiting nurse collect a COVID-19 lab specimen?**
   If a visiting nurse has an otherwise covered RHC or FQHC visit; they can obtain a sample to send to the laboratory for COVID-19 diagnostic testing.

7. **Can a Home Health Agency collect the COVID-19 lab specimen?**
   If a patient is already receiving home health services through Medi-Cal, the home health nurse, during an otherwise covered Medi-Cal visit, could obtain the sample to send to the laboratory for COVID-19 diagnostic testing.
8. What are the billable procedure codes for COVID-19 tests?

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Test</th>
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<tbody>
<tr>
<td>CPT 86328</td>
<td>Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method [e.g., reagent strip]</td>
</tr>
<tr>
<td>CPT 86769</td>
<td>Antibody; Severe Acute Respiratory Syndrome 2 [SARS-CoV-2] Coronavirus disease [COVID-19]</td>
</tr>
<tr>
<td>CPT 87635</td>
<td>Infectious agent detection by nucleic acid [DNA or RNA];</td>
</tr>
<tr>
<td>CPT 87426</td>
<td>Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA] qualitative or semiquantitative, multiple-step method; [SARS-CoV, SARS-CoV-2])</td>
</tr>
<tr>
<td>HCPCS U0001</td>
<td>CDC [SARS-CoV-2] Real-Time RT-PCR Diagnostic Panel</td>
</tr>
<tr>
<td>HCPCS U0002</td>
<td>Non-CDC laboratory tests for [SARS-CoV-2].</td>
</tr>
<tr>
<td>HCPCS U0003 and U0004</td>
<td>SARS-CoV-2 for the diagnosis of the virus that causes COVID-19 making use of high-throughput technologies.</td>
</tr>
<tr>
<td>HCPCS C9803</td>
<td>Hospital outpatient clinic visit specimen collection for [SARS-CoV-2] [COVID-19]. Used specifically for hospital outpatient departments to be reimbursed for specimen collection and symptom assessment for COVID-19 testing.</td>
</tr>
</tbody>
</table>

For the latest list of procedure codes, visit the Pathology Microbiology Provider Manual website.

9. Does Medi-Cal reimburse for COVID-19 testing for surveillance or employment purposes?

COVID-19 testing is a covered Medi-Cal benefit and can be provided to enrolled beneficiaries, based on medical necessity, as ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within their scope of practice as defined by state law or ordered by a physician but provided by a referral laboratory. Tests for the detection of SARS-CoV-2 or the diagnosis of COVID-19 are mandatory Medicaid laboratory services as described in the federal Social Security Act, Section 1905(a)(3) and the Code of Federal Regulations (CFR), 42 CFR 440.30.
10. Does Medi-Cal reimburse for At-Home COVID-19 tests?
Yes, at home COVID-19 tests are covered by Medi-Cal, when the test is ordered by an attending health care provider who has determined that the test is medically appropriate for the individual based on current accepted standards of medical practice. The AMA and CMS are adding testing procedure codes to the list on an emergent basis. Providers can bill Medi-Cal for at-home test when using the appropriate HCPCS/CPT code(s), and for now, CPT 87635.

11. What are the reimbursement rates for the COVID-19 tests?

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Medi-Cal Fee for Service Reimbursement Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 86328</td>
<td>$45.23</td>
</tr>
<tr>
<td>CPT 86769</td>
<td>$42.13</td>
</tr>
<tr>
<td>CPT 87635</td>
<td>$51.31</td>
</tr>
<tr>
<td>CPT 87426</td>
<td>$35.33</td>
</tr>
<tr>
<td>HCPCS U0001</td>
<td>$35.91</td>
</tr>
<tr>
<td>HCPCS U0002</td>
<td>$51.31</td>
</tr>
<tr>
<td>HCPCS U0003 and U0004</td>
<td>$100.00 each</td>
</tr>
<tr>
<td>HCPCS G2023</td>
<td>$23.46</td>
</tr>
<tr>
<td>HCPCS G2024</td>
<td>$25.46</td>
</tr>
<tr>
<td>HCPCS C9803</td>
<td>$22.99</td>
</tr>
</tbody>
</table>

12. Who can order COVID-19 tests?
California law (Business and Professions Code section 1288) requires that a clinical or public health laboratory accept assignments for clinical laboratory tests only from persons licensed under the provisions of law relating to the healing arts as healthcare providers with a scope of practice that authorizes ordering clinical laboratory tests or their representatives. On May 12, 2020, the Director of the Department of Consumer Affairs issued a waiver authorizing licensed pharmacists to order tests and collect samples for SARS-CoV-2 testing for the duration of the COVID-19 emergency, see question 11 below for additional information.

13. How do pharmacists get a CLIA certificate?
CDPH is the State agency with oversight of the CLIA program for laboratories in California. For more information contact:

California Department of Public Health
Division of Laboratory Science
Laboratory Field Services
320 West 4th Street, Suite 890
Los Angeles, CA 90013-2398
(213) 620-6160 or fax (213) 620-6565
Email: LFSCLIA@cdph.ca.gov
14. Can pharmacists be reimbursed for a COVID-19 test?
Medi-Cal will pay for COVID-19 tests performed by pharmacists as part of a laboratory enrolled in Medicare. A pharmacist also may furnish basic clinical services, such as specimen collection, when performed under contract with a doctor or practitioner, in accordance with a pharmacist’s scope of practice and state law. A pharmacy that acquires a Clinical Laboratory Improvement Amendment (CLIA) certificate can enroll with Medicare as a clinical diagnostic laboratory to conduct and bill for clinical diagnostic laboratory tests it is authorized to perform under its CLIA certificate. Pharmacists must enroll in Medi-Cal as a laboratory. For additional information on how to enroll as a clinical laboratory in order to provide services related to the COVID-19 emergency, please see the Requirements and Procedures for Emergency Medi-Cal Provider Enrollment. Applicants are required to have a CLIA appropriate for the level of testing being performed and a state laboratory license or registration in order to enroll as a clinical laboratory. A CLIA Certificate of Registration does not meet this requirement.