DHCS

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

WILL LIGHTBOURNE
DIRECTOR

GAVIN NEWSOM
GOVERNOR

DATE: December 9, 2020 (Supersedes November 24, 2020 version)
Changes are denoted with *******

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 for COVID-19: PCR, Serology and Antigen" 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 21, 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. Further, CDC posted a nursing home resource link that includes several publications regarding testing.

COVID-19 Testing Priority Populations
The CDPH, "Updated COVID-19 Testing Guidance" for public health officials, healthcare providers, and laboratories, includes a four-tiered system with information on who should be tested given the current context of the COVID-19 pandemic in California.

Medi-Cal COVID-19 Tests Procedure and Billing Information
Billing for a COVID-19 test is not dependent on the result of the laboratory test. All COVID-19 tests listed below can be billed to Medi-Cal. However, only a confirmed COVID-19 diagnosis must be billed with the applicable procedure code and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) U07.1. For additional guidance on COVID-19 coding, including coding for non-confirmed diagnosis, see the 2021 "ICD-10-CM Official Guidelines for Coding and Reporting, link.

Providers do not have to include an ICD-10-CM code on the billing form for a negative COVID-19 test, but can use ICD-10-CM code(s) that describe the signs/symptoms, viral screening code, or even the history of exposure instead. For instance, for "suspected," "possible," "probable," or "inconclusive" COVID-19, providers may consider assigning a code(s) that explain the reason for the encounter (such as fever) or Z20.828, Contact with and (suspected exposure to other viral communicable diseases.

On August 20, 2020, the Centers for Medicare and Medicaid Services (CMS) approved State Plan Amendment 20-0025. The SPA is in accordance with the CMS Interim Final Rule (IFR) for 42 CFR 440.30(d) to allow coverage of laboratory tests and x-ray services during the COVID-19 PHE and any future PHE, if the service is to diagnose or detect COVID or the communicable disease named in the PHE. Medi-Cal covers administering and processing COVID–19 laboratory and diagnostic tests in certain non-office settings, such as mobile testing sites, parking lots or other temporary outdoor locations, where the setting is intended to maximize physical distancing and thereby minimize transmission of COVID–19. Coverage also includes laboratory processing of self-collected test systems that the FDA has authorized for home use, without the order of a treating physician or other licensed non-physician practitioner (NPP). Laboratories that process self-collected test without an order, must notify the beneficiary and his/her physician or NPP, if known by the laboratory, of the results. This regulation (42 CFR 440.30(d) is for laboratory providers who are administering and processing COVID-19 testing in other settings, and they must meet the requirements for billing the applicable COVID-19 test.

On November 17, 2020, the FDA announced the first COVID-19 self-testing at-home kit. It is too soon for DHCS to provide guidance until more information is known.

As new COVID-19 procedure, diagnostic, and laboratory codes are announced by CMS, 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 Medi-Cal 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:

- California All COVID-19.CA.GOV website provides information on the statewide efforts to expand COVID-19 testing locations and includes COVID-19 laboratory resources. Medi-Cal providers including laboratories are encouraged to review these websites for additional testing information.

- On September 12, 2020, CDPH released guidance for all Californians on "Use of Antigen Tests for Diagnosis of Acute COVID-19." Also, the CDPH website includes 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
- https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf

DHCS Frequently Asked Questions

1. **Which COVID-19 tests are covered benefits?**
   Medi-Cal covers all 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?**
   Providers should follow the CDPH COVID-19 Updated COVID-19 Testing Guidance for public health officials, healthcare providers, and laboratories to determine when a test is necessary.

   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 are the billable procedure codes for COVID-19 tests?**

Procedure Code	Test
CPT 86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method [e.g., reagent strip]
CPT 86769	Antibody; Severe Acute Respiratory Syndrome 2 [SARS-CoV-2] Coronavirus disease [COVID-19]
CPT 87635	Infectious agent detection by nucleic acid [DNA or RNA]
CPT 86408 – effective 8/10/2020	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); screen
CPT 86409 – effective 8/10/2020	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); titer

CPT 86413 – effective 9/8/2020	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
CPT 87426	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)
CPT 87811 – effective 10/7/2020	Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
CPT 87636 – effective 10/7/2020	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
CPT 87637– effective 10/7/2020	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
HCPCS U0001	CDC [SARS-CoV-2] Real-Time RT-PCR Diagnostic Panel
HCPCS U0002	Non-CDC laboratory tests for [SARS-CoV-2].
HCPCS U0003 and U0004	SARS-CoV-2 for the diagnosis of the virus that causes COVID-19 making use of high-throughput technologies.
HCPCS G2023 and G2024	Specimen collection for COVID-19 testing. Billable by clinical diagnostic laboratories.
HCPCS C9803	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.

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

5. **What ICD-10 code should I include on a claim for a confirmed COVID-19 diagnosis?**
   ICD-10-CM U07.1 must be included on confirmed diagnosis claims.

6. **What is the frequency limit on COVID-19 tests?**
   Medi-Cal policies for most tests have a frequency limit of two per day, per patient for each code. CPT codes 86408 and 86409 have a frequency limit of one per

day, per patient for each code. These two new tests are specifically for neutralizing antibody tests and therefore only require one test.

7. **Can a practitioner receive payment for specimen collection?**
   Providers can be reimbursed for assessment and specimen collection for COVID-19 testing for a new or established patient using CPT 99211, or if the swab collection occurred in the physician's office, physicians can bill Medi-Cal with Evaluation and Management (E & M) CPT code 99000 for handling and/or conveyance of specimen for transfer from office to a laboratory.

8. **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.

9. **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.

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

Procedure Code	Medi-Cal Fee for Service[1] Reimbursement Rates
CPT 86328	$45.23
CPT 86769	$42.13
CPT 87635	$51.31
CPT 87426	$35.33
CPT 86408, effective August 10, 2020	$42.13

---

[1] DHCS will reimburse Medi-Cal FFS providers for COVID-19 testing based on the Medicare fee schedule. Unless otherwise agreed to between a managed care plan and the provider, DHCS encourages managed care plans to reimburse providers for COVID-19 testing at the Medicare fee schedule rates.

CPT 86409, effective August 10, 2020	$79.61
CPT 86413, effective September 8, 2020	TBD, check Medi-Cal fee schedule
CPT 87811, effective October 7, 2020	TBD, check Medi-Cal fee schedule
CPT 87636, effective October 7, 2020	TBD, check Medi-Cal fee schedule
CPT 87637, effective October 7, 2020	TBD, check Medi-Cal fee schedule
HCPCS U0001	$35.91
HCPCS U0002	$51.31
HCPCS U0003 and U0004	$100.00 each
HCPCS G2023	$23.46
HCPCS G2024	$25.46
HCPCS C9803	$22.99

11. **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.

12. **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.

13. **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. Pursuant to Executive Order N-39-20 issued by Governor Newsom, on August 25, 2020, the Department of Consumer Affairs, in collaboration with CDPH and the State Board of Pharmacy issued revised guidance to authorize pharmacies, acting within their scope of the waiver, to order, collect specimen, perform, and interpret results for authorized COVID-19 tests.

14. **Does Medi-Cal cover COVID-19 counseling?**
    Yes, in accordance with the CMS Provider Q & A, Medi-Cal providers who provide COVID-19 counseling to their patients, can bill with the applicable and existing codes to report counseling services, including E & M visits.

15. ***Can pharmacists be reimbursed for a COVID-19 test?**

A. Yes, Medi-Cal will pay for COVID-19 tests performed by a laboratory/pharmacy/pharmacist that has a Clinical Laboratory Improvement Amendment (CLIA) certificate; is enrolled in Medicare as a clinical diagnostic laboratory to conduct and bill for clinical diagnostic laboratory tests it is authorized to perform under its CLIA certificate; and is enrolled in Medi-Cal as a clinical laboratory.

B. In addition, a pharmacist may, in accordance with the pharmacist's scope of practice and state law, furnish basic clinical services, such as specimen collection, when the services are performed under "contract" with a doctor or practitioner.

C. A pharmacist can also contract with a pharmacy or laboratory that meets all of the requirements specified above in (A), and provide any COVID-19 related services that they are allowed to provide within their scope of practice and state law; however, under this scenario, Medi-Cal will reimburse the pharmacy/laboratory, not the pharmacist. The pharmacist will be paid according to the contracting arrangement between the pharmacy/laboratory and the contracting pharmacist.

Laboratories/pharmacies/pharmacists cannot bill Medi-Cal on a pharmacy claim as a pharmacy benefit and must bill the appropriate CPT or HCPCS code.

For additional information on how to enroll in Medi-Cal 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.

16. **How do pharmacists get a CLIA certificate?**
CDPH is the State agency with oversight of the CLIA program for laboratories in California. Pharmacists should review the guidance on the CDPH Laboratory Field Office website for additional information, or 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