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To: Medicaid Providers

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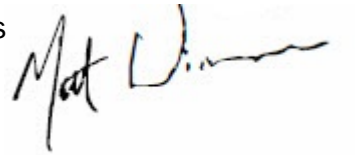

Subject: COVID-19: Laboratory and Pathology Services

The following are further details for Idaho Medicaid's policy on COVID-19 laboratory and pathology services.

Services must be medically necessary for coverage by Medicaid and reimbursement. Laboratory services should provide information that a clinician can use to initiate or change the management of a participant's care in a way that provides benefit to the tested participant. In the case of the COVID-19 public health emergency this is expanded to include additional considerations for other persons in the same setting (e.g., long-term care facilities) as outlined in this release. Services that are not medically necessary, such as those for employment, are not covered.

Per the Public Readiness and Emergency Preparedness Act (PREP Act) and Health and Human Services March 10 Declaration, pharmacists can order and administer tests for SARS-CoV-2. However, providers are reminded that they cannot bill for services rendered by another. If a pharmacist collects a specimen and sends it to a laboratory or another healthcare professional to test, the testing provider must be enrolled in Idaho Medicaid and bill the service directly.

CMS has granted some temporary flexibilities in their release "Laboratories: CMS Flexibilities to Fight COVID-19" that also apply to Medicaid. Rates paid for the services covered in the release will be at 90% of Medicare. The changes that apply include:

- Medicare COVID-19 Diagnostic Testing:
  - Laboratory Specimen Collection from Patient's Home;
  - Practitioner Payment for Specimen Collection;
  - Hospital Outpatient Payment for Specimen Collection;
  - Home Health Specimen Lab Collection;
  - RHC/FQHC Visiting Nurse Lab Specimen Collection; and
  - COVID-19 Diagnostic Testing.

In order to support recommendations of the State of Idaho Testing Task Force and the Idaho Rebounds plan, Medicaid is covering testing for SARS-CoV-2 based on this information release.

Testing for SARS-CoV-2 (Amended 08/31/2020)

COVID-19 is caused by infection with the virus SARS-CoV-2. Testing for SARS-CoV-2 includes molecular, rapid antigen and serologic (antibody) tests. Providers should educate participants on symptoms and prevention of COVID-19 when ordering either type of test. At a minimum, prevention education should include discussion of the importance and correct use of masks or face coverings, social distancing, hand washing, self-isolation and environmental cleaning. Recognized symptoms of a possible COVID-19 infection include fever, cough, shortness of breath, sore throat, chills, muscle pain, new loss of taste or smell, vomiting, and/or diarrhea.

Molecular testing demonstrating the presence of viral RNA is the only way to definitively diagnose an active infection with SARS-CoV-2. Molecular testing with reverse transcriptase polymerase chain reaction (RT-PCR) amplifies very small quantities of RNA specific to SARS-CoV-2 to detect the presence of the virus in the body. These tests may detect the virus 1–2 days before symptoms occur and for a short period after symptoms cease. Tests administered outside this window have a higher chance of returning false negative results. If clinical suspicion for COVID-19 remains high, self-isolation should be recommended regardless of test result. Molecular testing cannot determine if a person has recovered from a previous infection with the virus. Molecular tests available on the market include:

- Rapid molecular testing at the point of care for results within minutes (up to 4-5 per hour);
- High-throughput platforms that process large numbers of tests within hours (up to 2,000 per day);
- Out-of-state laboratories with capabilities similar to high-throughput platforms with turnarounds in 2–4-days.

Rapid antigen testing is less complex than molecular testing methods and can generally provide results in thirty minutes. Testing can be provided on site at a physician's office, retail pharmacy, or other locations with a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver. These tests are less sensitive than molecular testing and require approximately 100 times the amount of virus in the sample to be detected. This means they are most capable of providing an accurate diagnosis within the first five days of infection. These tests may not be effective five days after the onset of symptoms or for those that are asymptomatic. Positive tests are usually accurate and do not require additional testing. It is recommended that those with a negative result and a high degree of suspicion for infection be tested a second time with a molecular test and be told to isolate while awaiting the results of the follow-up test.

Serologic testing looks for previous infection with the virus by detecting the presence of antibodies that bind to viral proteins. The production of antibodies begins shortly after viral infection as part of the body's immune response. The IgM antibody begins production 5-7 days after the initial viral infection but may not be present in sufficient quantities for detection until

days later. The immune system begins production of the IgG antibody much later in the infection. The IgG antibody persists in the body for longer periods of time and may provide immunity to the virus. Some serologic tests incorporate both IgM and IgG antibodies while others test only for IgG. Antibody tests that look for IgG 3-4 weeks after the onset of symptoms are considered the most accurate; serologic tests are therefore not recommended for evaluating symptomatic patients. It is unclear the extent antibodies to SARS-CoV2 confer immunity to reinfection, and how long that immunity might persist. Some tests may have cross-reactivity with other coronaviruses and available tests vary significantly in sensitivity and specificity. In addition to choosing an antibody test for IgG and considering the timing of the test, it is important to use a test with high specificity to decrease the likelihood of a false positive result. Given the risks of a false positive antibody test, a second test should be performed to confirm the positive result. Serologic tests should never be used for diagnosing acute infection and currently have very limited clinical applicability.

Testing considerations for providers include sensitivity, specificity and prevalence of disease when determining which molecular, rapid antigen or serologic test to use. The sensitivity of a test reflects its ability to detect the presence of virus. The specificity of a test reflects its ability to confirm the absence of virus. It is important to remember that even a highly sensitive and specific test will lead to false positive results when the prevalence of disease is low. False positive results are especially problematic for serologic tests when patients might use those results to make decisions about social distancing. Prevalence of disease has to be very high for a serologic test to reliably confirm prior exposure to COVID-19; serologic testing therefore has very limited clinical applicability for most patients at this time. False negative results are quite frequent with molecular tests and especially with rapid antigen tests; patients with classic COVID-19 symptoms should be told to quarantine regardless of test results. As well, individuals exposed to a confirmed case of COVID-19 should be encouraged to self-isolate for 14 days even when test results for SARS-CoV-2 are negative, due to the long incubation period.

Covered Codes for the Collection of Specimens for COVID-19 Tests		
Codes	**Description**	**Effective Date**
Swab collection for specimens is included in evaluation and management codes.		
36415	Collection of venous blood by venipuncture	N/A
36416	Collection of capillary blood specimen (e.g., finger, heel, ear stick)	N/A
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source	03/01/2020
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source	03/01/2020
G2024	Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source	03/01/2020

Coverage of Rapid Antigen and Molecular Testing for SARS-CoV-2 (Amended 08/31/2020)
Rapid antigen and molecular testing is limited to four tests per month without a prior authorization. Only tests with an FDA Emergency Use Authorization are covered. Blanket orders for testing are not permitted.

Participants eligible for testing:

- Symptomatic participants;
- Participants exposed to confirmed or probable cases of COVID-19;
- Participants in group homes, homeless shelters, long-term or residential care facilities;
- Participants in the healthcare industry in contact with patients;
- Participants beginning or modifying treatment that could be affected by the presence of COVID-19;
- Participants discharging from one healthcare facility to another; and
- Participants undergoing the following diagnostic and therapeutic procedures:
    - Surgery;
    - Polysomnography with PAP titration;
    - Bronchoscopies;
    - Laryngoscopies;
    - Cardiovascular procedures that require anesthesia;
    - Gastrointestinal procedures; or
    - Imaging studies that require anesthesia.

Testing of participants outside of these criteria can be requested through a prior authorization from the Medical Care Unit.

Covered Codes for Molecular Testing for SARS-CoV-2		
Codes	**Description**	**Effective Date**
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; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19])	07/01/2020
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), amplified probe technique	03/13/2020
U0001	2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel-CDC	02/04/2020
U0002	2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel-NON-CDC	02/04/2020
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R.	04/14/2020

Covered Codes for Molecular Testing for SARS-CoV-2		
Codes	Description	Effective Date
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R.	04/14/2020

Coverage of Serologic Testing for SARS-CoV-2 (Amended 08/31/2020)
Serologic testing has limited clinical applicability and is at this point not recommended by the CDC or by the State of Idaho's Testing Task Force for use in directing patient care of COVID-19. Serologic testing is limited to twice per year without a prior authorization. Only tests meeting the following criteria are covered:

- Tests with an FDA Emergency Use Authorization;
- 99% or higher sensitivity; and
- 99% or higher specificity.

Participants eligible for testing:

- Evaluation of a recent past episode of symptoms (typically with onset 3-4 weeks prior) to determine if the infection was from the SARS-CoV-2 virus;
- The participant believes they are immune to the virus and are not following physical distancing guidelines, in order to document continued susceptibility and provide an opportunity for discussion about the importance of physical distancing; or
- Evaluation of a participant under the age of twenty-one for multisystem inflammatory syndrome in children (MIS-C) when the participant is admitted to the hospital with fever, laboratory evidence of inflammation, and clinically severe illness with multisystem organ involvement.

Claims for serologic testing must have a completed Serologic Testing for SARS-CoV-2 Documentation Form attached to be eligible for reimbursement.

Covered Codes for Serologic Testing for SARS-CoV-2		
Codes	Description	Effective Date
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (e.g., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	04/10/2020
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	04/10/2020

Non-Covered Codes (Added 08/31/2020)
The following codes are not covered under Idaho Medicaid:

Non-covered Codes		
Codes	Description	Effective Date
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen	08/10/2020
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer	08/10/2020

COVID-19 Resources (Amended 09/08/2020)
COVID-19 Testing Recommendations by Idaho Testing Task Force

Emergency Use Authorizations

EUA Authorized Serology Test Performance

Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)

FDA STATEMENT: Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts

Frequently Asked Questions about Laboratory Testing and COVID-19

Idaho Interim Guidance on Use of Rapid Antigen Tests for COVID-19

Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19

Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C)

Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19

Interim Guidelines for COVID-19 Antibody Testing

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