Blue Cross and Blue Shield of Louisiana
HMO Louisiana

May 4, 2020

Re: Coverage of Antibody Testing for COVID-19

Dear Provider:

Blue Cross and Blue Shield of Louisiana previously announced that we would cover diagnostic tests for the novel coronavirus (SARS CoV-2) and the illness it produces (COVID-19), without any out-of-pocket costs to members, as long as the tests are consistent with the U.S. Centers for Disease Control & Prevention (CDC) guidance and medically appropriate. We are further expanding this benefit change to include antibody testing.

Effective for dates of service April 10 through May 31, 2020, Blue Cross is waiving the deductible, coinsurance and copayment amount for medically appropriate antibody tests for SARS CoV-2 when ordered by a licensed provider practicing within the scope of their license. **During this timeframe, providers should not collect any cost share from members for this testing as Blue Cross will pay 100% of the allowable so there is no member cost share.**

At this time, we are not covering testing that is done solely for employment status determinations for fully insured members.

We have also enclosed a message from one of our medical directors to provide more detailed information on our COVID-19 testing strategy.

Proper Billing for Antibody Testing for SARS CoV-2

Blue Cross has established interim fees for antibody testing through May 31, 2020. The following CPT® codes should be used for an antibody test for SARS CoV-2:

- 86328 for an interim fee of $20 per test
- 86769 for an interim fee of $25 per test

More Online

Be sure to visit our COVID-19 Provider Resources page, where you can access all of our latest provider communications. Go to www.BCBSLA.com/providers, then click on the "COVID-19 Provider Resources" link at the top of the page. We will continue to add updated information to this page as it develops.

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5525 Reitz Avenue | Baton Rouge, Louisiana 70809 | **www.bcbsla.com**

Contact Us

If you have any questions about the billing of COVID-19, you may send an email to our Provider Relations Department at provider.relations@bcbsla.com. Please put "COVID-19 Billing" in the subject line.

Thank you for working with us to serve our members, especially during this time of uncertainty. We value you as a key part of our provider networks and the services you bring to our members—your patients.

Sincerely,

Hiral Arges
VP, Provider Relations and Contracting
Network Administration

Enclosure: Message on Managing the COVID-19 Testing Strategy

HA/jrm

Blue Cross and Blue Shield of Louisiana
HMO Louisiana

May 4, 2020

Dear Colleague,

Thank you for your dedication to our profession and the care you are providing to patients in this very unusual and difficult time. We are reaching out to you to ask for your assistance regarding managing the novel coronavirus (COVID-19) testing strategy. Collectively, our national health system has diagnosed and treated COVID-19 for less than four months. The science for appropriate management is ever evolving and often more questions than answers exist. Additionally, the concerns and anxieties of your patients and our members about this disease are extremely high. In this letter, we want to provide you with as much scientific information as possible about testing with an emphasis on the current state of antibody testing. The information is gleaned from several sources including peer reviewed journals, the World Health Organization (WHO), the U.S. Centers for Disease Control & Prevention (CDC), and numerous conversations and presentations regarding this topic with chief medical officers of major national labs and directors of state labs. Additionally, we are hoping to clarify BCBSLA's position on payment for testing and the use of testing in the strategy for return-to-work programs and opening our economy.

First, we would like to address the business aspects of the BCBSLA testing policy. The Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act both require insurers to cover the cost of tests for COVID-19 without a prior authorization and without a cost share (waiver of deductible, copayment or coinsurance) for the duration of the Public Health Emergency. BCBSLA is fully compliant with these Acts and covers these tests and associated services in this manner. Thus, as we have previously informed you, BCBSLA covers 100% of the allowable cost for the COVID-19 RT-PCR diagnostic test, serology/antibody tests, physician/urgent care/emergency department visits in which an RT-PCR or antibody test is ordered, and associated services to assist in determining the need for a COVID-19 test and diagnosis. We use our normal allowable rates and ask that you not collect a cost share from our members for these services. There are several exclusions to this payment policy:

- For fully insured group and individual members, our certificate of insurance excludes services required for occupational required exams or tests. Thus, we would not cover testing as part of a return-to-work program.
- For fully insured businesses that contract with us for a worksite wellness program, we cover preventive services that are Class A and B designated by the United States Preventive Services Task Force (USPSTF). The USPSTF has made no determination about COVID-19 virus or antibody testing and thus we would not cover testing as part of a worksite wellness program.
- We do not cover testing as part of a government sponsored and funded public health COVID-19 surveillance program. This is the financial responsibility of federal and/or state governments.
- We generally do not cover tests without a network provider's order. Thus, patient driven, home tests are generally not covered.
- ASO (self-insured) accounts have the freedom to adjust their benefits within guidelines and may elect to administer a return-to-work program through the claims process.

We have set allowable fees related to these covered tests. CMS has set the fee for the RT-PCR COVID-19 test. These amounts are generally set by a combination of the CMS fee at $51.31 for codes U0002 and 87635 and $100 for codes U0003 and U0004. Unfortunately, CMS has not yet set a fee for the antibody tests. To

temporarily set this fee, we reviewed the current allowable fee for all 89 other antibody tests in our fee schedule. The average allowable fee is $16.07 and the maximum for any of these tests was $25.70. This is in line with the potential fee we were quoted by a large, national lab. Consequently, through May 31, we have set a temporary allowable fee for CPT® code 86328 at $20 and for 86789 at $25.

There are some providers advertising antibody tests and charging patients an up-front fee of $100 or more. In these situations, they are not billing insurance. This is a violation of the network provider's contracts and we have had and continue to have many discussions with these providers informing them they must bill us for these services and not charge the member. Members who have received these tests and paid the provider directly may submit the bill to us for reimbursement. We will pay up to 100% of the allowable cost for the test and the provider evaluation. This may be less than what was charged to the patient. In that situation, the member would need to obtain a refund from the provider for the difference.

Second, we would like to provide information regarding the science and national policy regarding testing. As you are aware, the U.S. Food and Drug Administration (FDA) is responsible for the evaluation and approval of lab tests. This process normally is very rigorous and involves extensive independent evaluation of the test to ensure it is accurate and valid for the purpose intended. In a national emergency such as what exists today, the FDA has leeway to temporarily allow additional tests through an emergency use authorization (EUA) process. This process involves an application to the FDA and the submission and evaluation of data, but in an abbreviated fashion. The intent is to issue an EUA allowing the marketing of a test if the weight of the evidence suggests it is more likely than not that the test is safe and accurate. Several EUAs were issued for the real time polymerase chain reaction test (RT-PCR Test) to detect the RNA of the SARS CoV-2 virus. It is an extremely accurate test. False negatives are due to operator error in obtaining the test.

The situation, however, is quite different for the serology/antibody tests. For this test, the FDA put in place three processes. The first is the provision of an EUA as above for the RT-PCR test. Prior to last Friday, only four marketed antibody tests had received an EUA from the FDA. Secondly, they are allowing CLIA certified labs to develop and use Enzyme-Linked Immunosorbent Assay (ELISA) tests. These tests are also extensively validated. They can only be done in highly sophisticated labs that perform other ELISA tests, are quite accurate and are able to measure the quantity (titer) of an antibody. Generally, the specificity for these tests is in the 98.5% to 99.5%+ range. Over the weekend, the FDA has issued an EUA for an ELISA test from Roche. Additional tests from Abbot, Becton-Dickinson and Diasorin are expected to be approved shortly. The third approach was put in place due to concerns about the national emergency and involves a process in which a manufacturer applies for an EUA, validates the test in their own lab, notifies the FDA of its intent to market the test and agrees to specific labelling requirements. This has resulted in well over 100 Rapid Detection / Lateral Flow (Reagent Strip) tests hitting the market. As noted above, only four of these tests have been independently evaluated and issued an EUA. These tests are generally a reagent strip and can be done in either a lab or a physician's office. Unfortunately, there are several concerns with them including their sensitivities, which seem to run in the range of perhaps 90% to 96%. Additionally, they are not quantitative and only test for the presence or absence of IgM and IgG antibodies.

In order to evaluate the usefulness of antibody testing some basic information about the coronavirus and its immunology is essential. There are seven known coronaviruses that infect humans. Four of these (229E, NL63, OC43 and HKU1) cause up to 30% of the common cold each year. They are spread by the respiratory route, are highly contagious and immunity to them is very short-lived, usually lasting only a few months to a year. Thus, reinfection year-after-year with the same coronavirus is common. The other three coronaviruses

are also spread by the respiratory route but present their own problems in that each can cause a severe respiratory infection leading to death.

- SARS – the SARS CoV virus was present only in 2003-2004 and has not infected humans since. It infected about 8,000 people and had a case mortality rate approaching 10%. This virus contains very similar RNA and has 95% antigen cross-reactivity with the SARS-CoV-2 virus. Both IgM and IgG antibodies were produced to this virus at approximately the same time and the IgG antibodies appear to be protective against re-infection for an average of two years.
- MERS – according to the CDC, this infection first occurred in 2012 in Saudi Arabia. It, like SARS, is difficult to transmit from human-to-human. It persists today but is confined to the Arabian Peninsula. It has caused illness in only about 2,500 people but has a case mortality rate around 35%. There is no vaccine for it. The MERS CoV virus also generates antibodies that seem to convey immunity on average for a year or two.
- COVID-19 – this illness is the current pandemic and is caused by the SARS CoV-2 virus. As noted above, the virus has a very similar makeup to the SARS CoV virus and causes a severe respiratory infection in many patients. Its mortality rate is much lower at perhaps <1.0% to 4.0%. Unlike SARS and MERS, and more like the common cold, it is highly contagious and easily spread by the respiratory route. There is also a relatively high number of asymptomatic or mildly symptomatic cases. Until we understand those numbers, we cannot fully know the case mortality rate. Additionally, studies are showing that symptoms can develop between 1 and 14 days (most commonly 5 to 10 days) after exposure and more importantly that a person is often likely infectious up to five days before symptoms start and up to 6 weeks (more commonly a week or two) after symptoms resolve. The antibody production is similar to the SARS CoV virus with IgM and IgA antibodies being produced about five days after symptoms and lasting less than 10 days. IgG antibodies begin to develop around 14 days after symptoms and continue to rise. Obviously, we do not yet know how long those IgG antibodies persist.

There are some critical things that we do not yet know about COVID-19 and its immune response.

- A relatively small study from China demonstrated that perhaps as many as 7% of people who develop the COVID-19 infection appear to not develop any antibodies.
- The antibody used in the test must be specific to the virus that causes COVID-19 (SARS CoV-2) and not cross react with the four coronaviruses that cause up to 30% of the common cold or the SARS or MERS virus.
- We have no current scientific evidence that the antibodies we are currently detecting result in the person being immune to developing COVID-19 again. This question may be answered in the next several weeks.
- We have no current scientific evidence to know how much of the antibody (its titer) must be present to convey immunity.
- We have no current scientific evidence to know how long immunity will last if it develops.

This brings us back to the antibody test. A critical measure of the antibody test is its specificity. As you are aware, if the test is positive, the specificity represents the percent of time that the antibody is specific for the SARS-CoV-2 antibody and does not represent an antibody from another coronavirus. The presence of an antibody, however, does not mean the person is immune. We obviously want the specificity of these tests to approach 100%. An example of how this measure is used is illustrative. Let's assume there is scientific

evidence that a person with an antibody to COVID-19 is currently immune to the disease and cannot become re-infected. If the sensitivity of the test is 90% (similar to some of the tests on the market), if 100 people test positive for the antibody, only 90 people actually have it. So, 10 people do not have the antibody and are not immune. Further of those 100 people, we do not know which 10 are not immune. It is highly likely that a person who believes they are immune may let their guard down and take some chances. This could result in some people thinking they are immune, not taking appropriate measures to guard their safety or the safety of others around them and contracting COVID-19. The BCBSLA medical directors and many others around the country are raising this as a serious safety issue. In this case, a bad test may be worse than no test at all.

This leads to our request for your assistance. Based on the weight of the scientific evidence now, we are recommending the following:

- The RT-PCR test for COVID-19 is the test that should be used for the diagnosis of COVID-19. This is the appropriate test to also document that a person infected with COVID-19 has cleared the infection and is no longer currently infectious. An antibody test does not play any role in the diagnosis of an active infection.
- Testing for COVID-19 antibodies is extremely important from a public health perspective. This requires a coordinated state managed randomized sampling of the population to detect the incidence of the disease. Individual tests ordered by physicians should not be part of this effort.
- Testing for COVID-19 antibodies may have a role in retrospectively confirming a few cases in which COVID-19 was not diagnosed by RT-PCR and the patient is having unusual symptoms that may be explained by a previous or recovering COVID-19 illness.
- If a COVID-19 antibody test is needed, we strongly recommend the ELISA test be done with quantitative titers in a highly complex laboratory. We do not recommend the use of the Rapid Detection/Lateral Flow (Reagent Strip) tests for the reasons previously outlined.
- We do not believe COVID-19 antibody testing plays any role in a return-to-work strategy. At this point in time, the test is too unreliable and is not proven to convey immunity. There is a significant risk that individuals thinking they are immune could expose themselves and others to unnecessary risk of becoming infected with COVID-19. Indeed, BCBSLA has considered and rejected the concept of using antibody testing in our own return-to-work strategy.

We hope this information assists you in managing your patients and thank you for your dedication and commitment to providing highly effective, evidence-based care to our members.

Sincerely,

Thomas W Diller, MD

Thomas Diller, MD, MMM
VP, Population Health and Quality Transformation
Clinical Solutions