AdvaMedDx
Vital Insights | Transforming Care

June 11, 2020

VIA Electronic Mail: jeff.roe@premera.com

Mr. Jeff Roe
President and Chief Executive Officer
Premera Blue Cross
PO Box 91059
Seattle, WA 98111-9159

RE: Coverage for SARS-CoV-2 Serology Testing

Dear Mr. Roe:

On behalf of AdvaMedDx, we are writing to request that Premera Blue Cross revise its recently published, restrictive medical policy regarding SARS-CoV-2 serology (antibody) testing[1] for the reasons described below.

AdvaMedDx represents the world's leading diagnostics manufacturers by advocating for the value and power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

AdvaMedDx believes it is critical that physicians and other qualified healthcare professionals have access to the full array of SARS-CoV-2 testing, including diagnostic and serological antibody, antigen and other appropriate testing. Currently, many serology tests are offered under an Emergency Use Authorization (EUA) from the Food and Drug Administration, are authorized for the detection of antibodies against SARS-CoV-2, and are intended for use as an aid in identifying individuals with an adaptive immune response, indicating recent or prior infection.[2] Access to these tests is critical to support patients and the public health.

Premera Blue Cross has developed restrictive requirements that impede or prevent patient access to SARS-CoV-2 serology tests. However, federal law requires group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered plans) to cover tests for "the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19" when furnished with a EUA-authorized test.[3] Furthermore, federal guidance implementing this requirement explicitly states that plans and issuers must cover FDA-authorized COVID-19 serology tests:

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[1] https://www.premera.com/medicalpolicies/2.04.518.pdf
[2] *See* U.S. Food and Drug Administration, Emergency Use Authorizations (May 22, 2020), https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.
[3] Families First Coronavirus Response Act (Pub. L. No. 116-127), § 6001(a) (as amended by Coronavirus Aid, Relief, and Economic Security Act (Pub. L. No. 116-136), § 3201).

701 Pennsylvania Ave, N.W. | Suite 800 | Washington, D.C. 20004-2654
T - 202-783-8700 F - 202-783-8750 AdvaMedDx.org

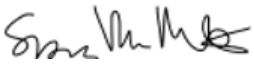
> *Serological tests for COVID-19 are used to detect antibodies against the SARS-CoV-2 virus and are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19. The Food and Drug Administration (FDA) currently believes such tests should not be used as the sole basis for diagnosis. FDA has advised the Departments that serological tests for COVID-19 meet the definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19.* ***Therefore, plans and issuers must provide coverage for a serological test for COVID-19 that otherwise meets the requirements of section 6001(a)(1) of the [Families First Coronavirus Response Act], as amended by section 3201 of the CARES Act.***[4]

Therefore, we urge Premera Blue Cross to immediately rescind or revise its policy and cover SARS-CoV-2 serology testing more broadly. Clinical laboratories may report the provision of FDA-authorized SARS-CoV-2 serology testing with *Current Procedural Terminology* (CPT) codes 86769 "*Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])*" or 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])*," as appropriate.

Testing has been evolving rapidly to keep up with this pandemic and with breakthroughs in science and technology. Serology testing, in particular, is critical to understanding this disease, community spread and the development of immune response in individuals and the population.

If you have any questions, please contact Chandra Branham, JD, at cbranham@advamed.org. Thank you in advance for your attention to this request.

Sincerely,



Susan Van Meter
Executive Director
AdvaMedDx

cc: Kitti Cramer, EVP and Chief Legal Officer, kitti.cramer@premera.com
Jim Messina, Chief Operating Officer, jim.messina@premera.com

[4] FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42 (Apr. 11, 2020), https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf, at Q4 (emphasis added).