Reimbursement Guide

for the Agena Bioscience® SARS-CoV-2 Panel

Agena Bioscience, Inc. developed the following reimbursement guide for healthcare providers who administer the Agena Bioscience® SARS-CoV-2 Panel for the identification of SARS-CoV-2 RNA in patients suspected of COVID-19 in the United States. We describe below our understanding of the coverage, coding and payment for administering the Agena Bioscience SARS-CoV-2 Panel as of August 5, 2020.

The information contained in this guide reflects Agena Bioscience, Inc.'s understanding of the current reimbursement landscape for diagnostic tests for COVID-19 and is for informational purposes only. It is not intended to suggest any manner in which healthcare providers can increase or maximize reimbursement from any payer. It is not intended to guarantee coverage, coding or payment. Reimbursement information is gathered from third-party sources and is subject to change. Recent changes in applicable law, regulations and policies may not be reflected in the information contained herein and healthcare providers should check applicable laws and regulations. Agena Bioscience, Inc. recommends that healthcare providers consult with individual payers for specific coverage, coding and payment information. Healthcare providers are ultimately responsible for determining appropriate charging and billing practices.

About The Agena Bioscience SARS-CoV-2 Panel

The Agena Bioscience SARS-CoV-2 Panel, for use on the MassARRAY® System, is a multiplex Reverse Transcription Polymerase Chain Reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2. The Agena Bioscience SARS-CoV-2 primer and probe sets are designed to detect RNA from SARS-CoV-2 in upper respiratory samples (nasopharyngeal swab, oropharyngeal swab) and lower respiratory bronchoalveolar lavage (BAL) samples from individuals suspected of COVID-19 by their healthcare providers.

The Agena Bioscience SARS-CoV-2 Panel is pending FDA review for use under Emergency Use Authorization (EUA) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb-3). FDA has been notified that the Agena Bioscience SARS-CoV-2 Panel is validated pursuant to Section IV.C. of FDA's Policy for Coronavirus Disease-2019 Tests.

The Agena Bioscience SARS-CoV-2 Panel is for use in U.S. laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

The MassARRAY System consists of a Matrix-Assisted Laser Desorption Ionization – Time of Flight (MALDI-TOF) mass spectrometer (the MassARRAY Analyzer) customized for the precise detection of DNA molecules. Data acquired by the MassARRAY Analyzer is processed by MassARRAY Typer software, and then the SARS-CoV-2 Report software. The MassARRAY System is available in both 96-well and 384-well formats. In a 24-hour period, the MassARRAY System can provide results for a maximum of 2,112 and 6,114 samples, respectively.

Positive results generated by the Agena Bioscience SARS-CoV-2 Panel are indicative of the presence of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in upper respiratory and BAL samples during the acute phase of infection. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results generated by the Agena Bioscience SARS-CoV-2 Panel do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

For more information on the Agena Bioscience SARS-CoV-2 Panel, please consult the Instructions for Use located here.

Coverage

Coverage is a payer's determination that items and services are medically necessary for a patient and may be included under the patient's health insurance benefits. Coverage varies by payer. Healthcare providers should consult with individual payers regarding their coverage policies, including any applicable coverage criteria or documentation requirements.

Medicare Program:

Medicare Part B and Medicare Advantage plans generally cover tests to diagnose or aid the diagnosis of COVID-19. For COVID-19 covered tests, there is no deductible, coinsurance or copayments.[1] It is recommended that healthcare providers consult with applicable local Medicare Administrative Contractors and Medicare Advantage plans regarding coverage of the Agena Bioscience SARS-CoV-2 Panel.

[1] See Medicare.gov website here.

State Medicaid Programs:

There is likely Medicaid coverage for the Agena Bioscience SARS-CoV-2 Panel. Section 6004(a) of the Families First Coronavirus Response Act (FFCRA), enacted on March 18, 2020 (Pub. L. No. 116-127 (2020), added a new mandatory benefit in the Medicaid statute, at section 1905(a)(3)(B) of the Social Security Act, and this provision was amended by section 3717 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), enacted on March 27, 2020 (Pub. L. No. 116-136 (2020)). Section 1905(a)(3)(B) of the Social Security Act provides that, for any portion of the COVID-19 emergency period defined in section 1135(g)(1)(B) of the Social Security Act that begins on or after March 18, 2020,[2] Medicaid coverage must include in vitro diagnostic products (as defined in FDA regulations at 21 C.F.R. § 809.3(a)) for the detection of SARS-CoV-2 or diagnosis of COVID-19, and the administration of such in vitro diagnostic products. While the section 1905(a)(3)(B) benefits end upon conclusion of the emergency period (and any extensions thereof), states can continue to cover COVID-19 testing under the section 1905(a)(3)(A) mandatory laboratory services benefit after the emergency period ends.[3]

Commercial Health Insurance (Group Health Plans and Health Insurance Issuers):

There is likely commercial coverage of the Agena Bioscience SARS-CoV-2 Panel. Section 6001 of the FFCRA, as amended by the CARES Act, generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for certain items and services related to diagnostic testing for the detection of SARS-CoV-2 or the diagnosis of COVID-19 when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period. These items and services include the following tests:

- Tests that are approved, cleared or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 360(k), 360c, 360e, 360bbb-3);

- The test developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360bbb-3), unless and until the emergency use authorization request

[2] On January 31, 2020, HHS Secretary Alex M. Azar II declared that as of January 27, 2020, a public health emergency exists nationwide as the result of the 2019 novel coronavirus. On April 21, 2020, the HHS Secretary renewed the COVID-19 public health emergency declaration, effective April 26, 2020. On July 23, 2020, the HHS Secretary again renewed the COVID-19 public health emergency declaration, effective July 25, 2020. See Public Health Emergency Declarations here. The Secretary may extend the public health emergency declaration for subsequent 90-day periods for as long as the public health emergency continues to exist, and may terminate the declaration whenever he determines that the public health emergency has ceased to exist.

[3] See COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies (June 30, 2020) here.

under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;

- The test is developed in and authorized by a State that has notified the Secretary of HHS of its intention to review tests intended to diagnose COVID-19; or

- Other tests that the Secretary of HHS determines appropriate in guidance.

Under the FFCRA, plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments and coinsurance) or prior authorization or other medical management requirements.[4]

Coding

Coding enables healthcare providers to communicate to payers the items and services furnished to a patient in order to obtain payment for those items and services. It is the responsibility of the healthcare provider to determine the most appropriate codes to report on a claim, upon consultation of specific payer policies.

Based on currently available information, the Agena Bioscience® SARS-CoV-2 Panel may be described by the following HCPCS code:

> *HCPCS code 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.*

HCPCS code U0003 is intended to identify tests that would otherwise be identified by CPT code 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) but for being performed with high throughput technologies.

Payment

Payment is the amount that a payer renders to a healthcare provider for furnishing items and services to a patient. Patients may also have cost-sharing obligations, including deductibles, coinsurance or copayments, depending on their health insurance benefits. Payment amounts vary by payer and by geographic location, and are frequently updated. Healthcare providers should consult with individual payers regarding applicable current payment amounts.

[4] See FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief and Economic Security Act Implementation Part 43 (June 23, 2020) here.

HCPCS code U0003 is currently assigned a Medicare Part B payment rate of $100 per test.[5]

Section 3202(a) of the CARES Act generally requires commercial health insurers (plans and issuers) providing coverage for diagnostic items and services to reimburse any provider of COVID-19 diagnostic testing an amount that equals the negotiated rate or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on a public website. (The plan or issuer may negotiate a rate with the provider that is lower than the cash price.) Additionally, during the public health emergency related to COVID-19, section 3202(b) of the CARES Act requires providers of diagnostic tests for COVID-19 to make public the cash price of a COVID-19 diagnostic test on the provider's public internet website.[6]

It is recommended that healthcare providers consult with individual payers regarding payment rates for the Agena Bioscience SARS-CoV-2 Panel.

Additional Information

In providing this reimbursement guide, Agena Bioscience, Inc. makes no warranties, express, implied or statutory, including, but not limited to, warranties of merchantability, fitness for a particular purpose and/or non-infringement. Agena Bioscience, Inc. assumes no responsibility for omissions or errors contained in this reimbursement guide. This guide presents no promise, commitment, statement or guarantee by Agena Bioscience, Inc. concerning proper billing or coding practices or levels of payment or charges. This information does not constitute reimbursement or legal advice. The existence of codes does not guarantee coverage or payment for any procedure by any payer. The healthcare provider is ultimately responsible for determining the appropriate coverage, coding and payment policies for individual patients.

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[5] See CMS Ruling CMS-2020-01-R here.
[6] See FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief and Economic Security Act Implementation Part 43 (June 23, 2020) here.

For additional information, please contact Agena Bioscience, Inc.'s reimbursement helpline at ScientificAffairs@agenabio.com.

Agena Bioscience, Inc. does not recommend codes for specific cases. Agena Bioscience, Inc. does not promote the off-label use of its diagnostic tests.

For more information regarding Agena Bioscience, Inc. or the Agena Bioscience SARS-CoV-2 Panel, please visit our website: **agenabio.com**.

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