COVID-19 Reimbursement Toolkit

Thank you for trusting Quidel for your COVID-19 rapid testing needs.

Given the unprecedented times of this public health emergency (PHE), your site may be experiencing challenges in testing and treating patients. **To date, many of the reimbursement issues we have helped customers with revolve around a disconnect and lag of various systems and processes at play, such as the FDA, AMA, CMS, private and government payers, and customer's own internal and external processes.** We hope you will find this COVID-19 Reimbursement Toolkit helpful in navigating this continually evolving pandemic landscape.

Testing

Congress has enacted legislation (FFCRA and CARES) that **requires insurers to cover testing for the detection of SARS-CoV-2, including diagnostic test panels and other medically necessary services, on or after 03/18/20** and during the applicable emergency period, without any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements, and to reimburse providers at an amount equal to the negotiated plan rate, **OR** the provider's publicly published cash price. Although insurers may, they are not *required* to provide coverage of testing for public health surveillance or general employment purposes. Plans must, however, cover *all* COVID-19 diagnostic tests (that meet one of the criteria outlined in section 6001 of the FFCA[1], as amended by section 3201 of the CARES[1]), including point-of-care tests, for the purpose of individualized diagnosis or treatment of COVID-19, even for asymptomatic individuals. Furthermore, required coverage does not limit the number of diagnostic tests for an individual, provided that the tests are diagnostic and medically appropriate.[1]

The FDA issued an Emergency Use Authorization (EUA) to Quidel for the **Sofia SARS Antigen FIA and the Sofia 2 Flu + SARS Antigen FIA**.[2] The Sofia SARS Antigen FIA test is performed on the Sofia or Sofia 2 Fluorescent Immunoassay Analyzer using nasal or nasopharyngeal specimens and results in qualitative detection of nucleocapsid protein from SARS-CoV-2 within 15 minutes. The Sofia 2 Flu + SARS Antigen FIA test is performed on the Sofia 2 Fluorescent Immunoassay Analyzer using nasal or nasopharyngeal specimens and results in the qualitative detection of nucleocapsid protein from influenza A and influenza B, and SARS-CoV-2 within 15 minutes.

Coding and Payment

To describe the COVID **SARS Antigen test**, the AMA[3-5] approved new **CPT® Code 87426**, which is defined as*: Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]).*

To describe the **Flu + SARS Antigen test,** the AMA[3-4,6] approved the new **CPT® Code 87428,** which is defined as: *Infectious agent antigen detection by immunoassay technique, (e.g., enzyme, immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric SARS-CoV, SARS-CoV-2 [COVID-19] and influenza virus types A and B.*

For the duration of the PHE declaration, EUA tests, when authorized by FDA for use at the Point of Care (POC) in a patient-care setting that is operating under a CLIA Certificate Waiver, Certification of Compliance, or Certificate of Accreditation are eligible to be performed in CLIA waived laboratories. To be recognized as a test that can be performed in a facility possessing a CLIA Certificate of Waiver, the modifier QW must be appended to the claim (**87426-QW or 87428-QW**).[2,5-6]

Suggested Reimbursement Preparations Prior to Submitting COVID-19 Claims

- Establish your **cash price for COVID-19 testing** and publish it to your public website.
- **Contact your payers** to: (a) ensure their system has been updated with the new CPT codes 87426, 87428, 87426-QW, 87428-QW and (b) negotiate the provider/payer contract to include an appropriate payment rate for the tests. Note that CMS has indicated the effective date of the adding the QW modifier to 87426 is 06/25/2020, and the implementation date is 10/05/2020. For 87428, the effective date is 10/06/2020, and the implementation date is 04/05/2021. Payers may not have the coding update(s) in their system prior to the effective date(s). It is recommended to contact your payer prior to submitting to ensure they have implemented the necessary update(s) in their system.
- **Provide a current version of the COVID-19 Reimbursement Toolkit to your A/R Team**. Your Office Manager, Billing Department, Claims Clearinghouse, EHR, and other third-party claims/payment vendor(s) need to be aware of the new COVID-19 tests you are utilizing and the new CPT codes and modifier (if operating under a CLIA Certificate Waiver) so they can update their system(s) and process(es). Encourage your A/R team to utilize the resources provided herein to reference important CLIA information and enacted legislation as it pertains to COVID-19 testing and to alert you as reimbursement challenges arise so that issues can be resolved in a timely manner.

Common COVID-19 Denials and Solutions

Although 87426 and 87428 are now established codes, they will not be published until the 2022 CPT Manual update. Therefore, some payers may issue "**CPT Code Invalid**" denials until their systems are updated to reflect the new codes.

- Billers may need to provide the AMA CPT Code 87426 and 87428 resources (see Resource List below) to the payer, request the claim be reprocessed with the current CPT code additional information, and/or submit an appeal. Contact us for an appeal template.

It is important to note that in a non-pandemic environment, CMS typically maintains a full list of CLIA-waived tests. However, CMS is not actively updating that list with each EUA COVID-19 test approved by the FDA and may deny as "**Procedure Code is Outside the Scope of this Department's Waived Level CLIA Certificate**" or "**Missing Procedure Modifier**".

- Customers possessing a CLIA Certificate Waiver should ensure their Billers are billing the Sofia SARS Antigen FIA and the Sofia 2 Flu + SARS Antigen FIA with the modifier QW (**87426-QW or 87428-QW**), using the **CMS MLN Matters QW Modifier resources** (see Resource List below[2-6]).
- Customers should also ensure their Claims Clearinghouse is aware of the **FDA Approved EUA Tests and CMS MLN Matters QW Modifier resources** (see Resource List below[2-6]) so that appropriate flags and edits

can be applied to claims software. Clearinghouses often alert you of flags in the system that *may* result in claim denials. These systems should allow bypass of the edit, as appropriate or necessary.

- Billers may need to provide **the CMS MLN Matters QW Modifier and/or FDA Approved EUA Test resources** (see Resource List below) to the payer, request the claim be reprocessed with the additional information, and/or submit an appeal. Contact us for an appeal template.
- As is the case with all Quidel products, we offer a dedicated Reimbursement Team to answer questions, support customers and provide appeal templates. Should you need assistance or resources, contact our CodeMap® Reimbursement Support Team at **312.291.8408** or quidel@codemap.com.

Denial Resources

[1] CMS FFCRA & CARES FAQs:
https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf
https://www.cms.gov/files/document/faqs-part-44.pdf

[2] FDA Approved EUA Tests: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev (Note the Quidel SARS Antigen FIA and Flu + SARS Antigen FIA are allowed in H, M or W Authorized Setting(s), indicating use by laboratories meeting requirements to perform high complexity tests, moderate complexity tests, and patient care settings operating under a CLIA Certificate of Waiver).

[3] AMA COVID-19 CPT Coding and Guidance:
https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-coding-and-guidance

[4] AMA CPT Assistant: https://www.ama-assn.org/system/files/2020-11/cpt-assistant-guide-coronavirus-november-2020.pdf

[5] CMS MLN Matters QW Modifier (87426): https://www.cms.gov/files/document/mm11927.pdf

[6] CMS MLN Matters QW Modifier (87428): https://www.cms.gov/files/document/mm12093.pdf

General Resources

CMS Coronavirus (COVID-19) Partner Toolkit:
https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit

America's Health Insurance Plans (AHIP) Providers Respond to COVID-19:
https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19

For **questions, please contact**
CodeMap® Reimbursement Support:

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MI20374003EN00 (03/21)