Important Updates Regarding the Approval of the Pfizer-BioNTech COVID-19 Vaccine, the Authorization for a Third Dose of mRNA COVID-19 Vaccines, the HRSA COVID-19 Claims Reimbursement Program, Guidance on Appropriate Use for COVID-19 Tests, and COVID-19 Reporting

August 27, 2021

FDA Approves Pfizer-BioNTech COVID-19 Vaccine for Individuals 16 Years of Age and Older

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the first COVID-19 vaccine for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine, previously known as the Pfizer-BioNTech COVID-19 Vaccine, will now be marketed as Comirnaty (koe-mir'-na-tee). The vaccine also continues to be available under emergency use authorization (EUA), for individuals 12 through 15 years of age. You can read the FDA news release regarding the approval here.

Additional Resources

- Comirnaty Prescribing Information
- Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA

FDA Authorizes Third Dose of mRNA COVID-19 Vaccines

On August 12, 2021, the FDA amended the EUAs for both the Pfizer-BioNTech and Moderna COVID-19 vaccines to allow for the use of a third dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. You can read the FDA news release regarding the update here.

Per the updated EUAs:

- For the Pfizer-BioNTech COVID-19 vaccine, a third dose can be administered at least 28 days following the two-dose regimen of this vaccine in certain immunocompromised individuals 12 years of age or older. You can read the updated EUA for the Pfizer-BioNTech COVID-19 vaccine here.

- For the Moderna COVID-19 vaccine, a third dose can be administered at least 28 days following the two-dose regimen of this vaccine in certain immunocompromised individuals 18 years of age or older. You can read the updated EUA for the Moderna COVID-19 vaccine here.

HRSA COVID-19 Claims Reimbursement Program

The Health Resources and Services Administration (HRSA) COVID-19 Claims Reimbursement Program provides claims reimbursement to health care providers who provide COVID-19 testing, treatment for COVID-19, and COVID-19 vaccine administration to uninsured individuals. The program aligns claims reimbursement for monoclonal antibody therapy with the Centers for Medicare and Medicaid Services (CMS) guidance issued on November 10, 2020. Per CMS's Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction, "During the COVID-19 public health emergency,

Medicare will cover and pay for these infusions the same way it covers and pays for COVID-19 vaccines (when furnished consistent with the EUA)." Information regarding coding and pricing can be found in the Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction.

For billing codes specific to COVID-19 testing, treatment, and vaccine administration for the uninsured, click on this link: https://coviduninsuredclaim.linkhealth.com/billing-codes.html.

Guidance on Appropriate Use for COVID-19 Tests

Diagnostic tests for COVID-19 should be used in the same manner specified by FDA's EUA or approval. Tests include molecular tests and antigen tests.

Antigen diagnostic tests should only be used for persons experiencing symptoms consistent with COVID-19. The only current exception is the Ellume COVID-19 Home Test, which can also be used for persons who are asymptomatic. For more information regarding antigen diagnostic tests, please click here.

All molecular diagnostic tests can be used for both symptomatic and asymptomatic persons. For more information regarding molecular diagnostic tests, please click here.

For questions, please contact your county health department. A list of county health departments and their reporting contact information can be found at www.FLhealth.gov/chdepicontact.

COVID-19 Reporting

On August 18, 2021, Florida Administrative Code rule 64D-3.029, was updated regarding COVID-19 reporting. COVID-19 antibody test results are no longer required to be reported to the Florida Department of Health (Department). All COVID-19 antigen or molecular test results (positive, negative and inconclusive) are still required to be reported electronically; however, only the positive result is required to be faxed while onboarding to electronic laboratory reporting with the Department.

To enroll in electronic laboratory reporting, visit http://floridahealth.gov/electronicreportingregistration.

Prior to enrolling in electronic laboratory reporting, positive COVID-19 antigen and molecular test results must be faxed to your county health department. A list of county health departments and their reporting contact information can be found at www.FLhealth.gov/chdepicontact. Once your facility can effectively report COVID-19 test results electronically to the Department, all COVID-19 antigen and molecular results must be reported to the Department.