IMMUNIZATION
COVID-19 UPDATE

ISSUE NO 42 | JANUARY 6, 2022

QUESTION OF THE WEEK:

How long should someone quarantine or isolate if they were exposed to someone or infected with COVID-19?

As of this week, CDC has posted the updated COVID-19 quarantine and isolation guidance on the CDC website. These updated recommendations come as the Omicron variant is now rapidly spreading throughout the United States causing very high case rates.

The recommendations reflect the societal impact (e.g., critical infrastructure and staffing shortages) and the latest science on disease severity and when and for how long a person is maximally infectious.

Select an option below to view the CDC guidance on isolation and quarantining:

- General Public & Workplaces
- K-12 Schools
- Healthcare Settings
- Correctional Institutions
- Homeless Shelters

COMPLETED VACCINE SERIES IN LOUISIANA

2,338,514*

***4,809,714 total doses administered in Louisiana**

NEW COVID-19 BOOSTER & ADDITIONAL DOSE GUIDANCE

CDC recommends new waiting period of 5 months to receive booster dose for those fully vaccinated with the Pfizer vaccine. Kids 12-17 years old are now able to receive a booster dose when eligible. (Page 2)

NEW ADOLESCENT AND ADULT PFIZER VACCINE FORMULATION

A new formulation of the Pfizer vaccine (gray cap) will be made available to order by providers that does not require diluent. (Pages 2-3)

WEEKLY COVID-19 VACCINE UPDATE

New COVID-19 Vaccine Booster Dose/Additional Dose Guidance

The U.S. Centers for Disease Control and Prevention (CDC) updated its recommendations for the Pfizer/BioNTech COVID-19 vaccine booster Wednesday, January 5, 2022, to include children as young as 12 receiving a booster at least five months after they finish the Pfizer-BioNTech vaccine series.

The Louisiana Department of Health (LDH) announces that effective immediately:

- **Individuals 12 to 17 years old are recommended to receive a booster shot** five months after completion of their initial Pfizer-BioNTech vaccination series. At this time, only the Pfizer-BioNTech COVID-19 vaccine is authorized for 12 to 17 year olds.
- **The booster dose interval of six months after initial series completion has been shortened to five months** for all individuals ages 18 and older who have completed the Pfizer-BioNTech COVID-19 vaccine series. This means that individuals can now receive an mRNA booster (Pfizer or Moderna) dose five months after completing the initial Pfizer-BioNTech series.
    - The booster interval recommendation for people who initially received the Johnson & Johnson or Moderna vaccines remains the same (2 months for J&J and 6 months for Moderna).
- **Moderately or severely immunocompromised children ages 5 to 11 are eligible to receive an additional primary (or third) dose of vaccine** 28 days after completing the Pfizer-BioNTech vaccine series. As a reminder, only the Pfizer-BioNTech COVID-19 vaccine is currently authorized for 5 to 11 year olds. To see what qualifies as immunocompromised, go to cdc.gov.

LDH reminds providers to report any possible vaccine-related adverse events to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov or by calling 1-800-822-7967.

Any possible severe adverse events (those resulting in hospitalization, death, or persistent disability) should be immediately reported to the Office of Public Health (OPH) Infectious Disease/Epidemiology hotline at 1-800-256-2748.

If you have additional questions, email la.immunization@la.gov.

New Adolescent and Adult Pfizer Vaccine Formulation

Starting this week, a new formulation of Pfizer vaccine for adults and adolescents will be made available, the Pfizer-BioNTech **GRAY** cap formulation. The Pfizer-BioNTech **PURPLE** cap formulation will no longer be available for providers to order.

This formulation involves some changes to ordering and handling:

- The minimum order for direct shipment is now 300 doses. Providers can still order smaller quantities (as little as one vial of vaccine) through Morris & Dickson.
- This product **DOES NOT REQUIRE DILUENT**. Providers will no longer receive diluent with their ancillary supplies for this product and should not dilute any **GRAY** cap Pfizer vaccine.
- This product **CANNOT BE STORED IN THE FREEZER**.
    - Direct vaccine shipments will arrive ultra-cold. Vaccine received this way can either be stored in an ultra-low temperature (ULT) freezer for up to 9 months or moved to the refrigerator for up to 10 weeks.
    - Morris & Dickson vaccine shipments will arrive refrigerated. Vaccines received this way can only be stored in the refrigerator for up to 10 weeks. **DO NOT REFREEZE**.

Vial Storage During Use:

- The vaccine does not contain preservatives and is provided as a multi-dose vial.
- Each vial must be thawed prior to administration.
- **DO NOT DILUTE** prior to use.
- One vial contains 6 doses of 0.3mL.
- **GRAY** cap may be stored at room temperature for a total of 12 hours prior to the first puncture.
- After the first puncture, the vial should be held between 2° to 25°C (35° to 77°F).
- Vials should be discarded 12 hours after the first puncture.
- During storage, minimize exposure to room light and avoid exposure to direct sunlight and UV light.

The Pfizer **GRAY** cap formulation is an approved alternative to the Pfizer **PURPLE** cap formulation. This means if an individual received their first dose of the diluted **PURPLE** cap formulation, they can receive their second dose (or booster) with the non-diluted **GRAY** cap formulation.

The date of manufacture is printed on the vials, not the expiration date, similar to the Pfizer pediatric **ORANGE** cap formulation.

- To determine the expiration date for the ULT direct shipped vaccine, count 9 months from the date of manufacture, including the month of the date of manufacture in the calculation. For example, if September 1, 2021, is printed on the vial, the vaccine would expire on May 21, 2022.
- To determine the expiration date for the refrigerated Morris & Dickson shipped vaccine, count 10 weeks from the day you received the vaccine. Please note, the true 9-month expiration date should still be logged in LINKS.

The GRAY cap formulation will be shipped in the same single-sue thermal shippers as the ORANGE cap formulation. Single-use thermal shippers cannot be used for temporary storage.

Any PURPLE cap vaccine still on hand (and has not expired) is still viable for use and should not be discarded. Any and all PURPLE cap vaccine should be utilized first before GRAY cap vaccine to prevent overlap and errors.

For more information on Pfizer-BioNTech COVID-19 vaccine, visit cvdvaccine-us.com.

You can also view the attached Vaccine Formulation and Presentation Guide for Pfizer-BioNTech COVID-19 Vaccine quick reference guide found at the end of this newsletter for more information on the differences in vaccine formulations.

COVID-19 Testing Sites in Louisiana

With Omicron cases increasing, so has the need for COVID-19 testing. You should get tested if:

- You have COVID-19 symptoms
- You were exposed to COVID-19
- You plan on traveling soon
- Asked by a healthcare professional or public health official

To find a COVID-19 testing site near you, go to ldh.la.gov. This resource offers an interactive map, separated by parishes, to assist you in finding a testing site nearest to you.

For more information on COVID-19 testing or to use the CDC's Coronavirus Self-Checker tool and COVID-19 Viral Testing Tool, go to cdc.gov.

LOUISIANA COVID-19 VACCINE DEMOGRAPHICS

SERIES COMPLETED BY RACE:

- **White:** 58.46%
- **Black:** 31.14%
- **American Indian:** 0.41%
- **Asian:** 2.82%
- **Native Hawaiian:** 0.19%
- **Unknown:** 1.21%
- **Other:** 5.77%

SERIES COMPLETED BY AGE:

- **5-17:** 6.4%
- **18-29:** 13.12%
- **30-39:** 13.44%
- **40-49:** 13.83%
- **50-59:** 16.47%
- **60-69:** 18.37%
- **70+:** 18.37%

SERIES COMPLETED BY GENDER:

- **Female:** 54.12%
- **Male:** 45.63%
- **Unknown:** 0.25%

All breakdowns shown here are for Louisiana residents only. Race data completeness is expected to improve as we continue our outreach with vaccine providers.

Good Reads

CDC recommends COVID-19 booster shots for eligible teens 12 and older – This article talks about how the CDC is encouraging Pfizer booster doses for teens 12 to 15.

Read more at nola.com.

COVID infections hit another daily record in Louisiana as hospitalizations rise – This article talks about how the number of patients increasingly rises at a record-breaking pace in Louisiana.

Read more at nola.com.

Omicron surge vexes parents of children too young for COVID vaccine – This article talks about how parents of young children are facing difficult choices as the Omicron variant increases COVID-19 infections making every encounter risky.

Read more at nola.com.

Vaccine Formulation/Presentation Guide

For further details about the Pfizer-BioNTech COVID-19 Vaccine, please see appropriate Fact Sheet or contact US Medical Information at PfizerMedicalInformation.com or 1-800-438-1985.

Children ages 5 through 11 years old should only be vaccinated with the Ages 5 through 11 years ("Age 5y to <12y" on vial label) DILUTE BEFORE USE Orange Cap presentation. **No other vaccine presentation should be used for children 5 through 11 years old because of the potential for vaccine administration errors, including dosing errors.** For children who will turn 12 between their first and second dose, consult the EUA Fact Sheets for Vaccination Providers.

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the 2 EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older[1,2]	12 years and older[3]	5 through 11 years[4] ("Age 5y to <12y" on vial label)
Vial Cap Color	Purple 	Gray 	Orange 
Dose	**30 mcg**	**30 mcg**	**10 mcg**
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial*	1.8 mL	**NO DILUTION**	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)
Storage Conditions			
Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]	9 months†	6 months‡	6 months‡
Freezer [-25°C to -15°C (-13°F to 5°F)]	2 weeks	**DO NOT STORE**	**DO NOT STORE**
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month	10 weeks	10 weeks
Room Temperature [8°C to 25°C (46°F to 77°F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2°C to 25°C (35°F to 77°F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours

*ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
†Regardless of storage condition, vaccine should not be used past the 9-month expiry (6 months printed on the vial plus additional 3 months).
‡Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.

Emergency uses of the vaccine have not been approved or licensed by FDA but have been authorized to prevent COVID-19 in ages 5+.

Please see Important Safety Information and Indication & Authorized Use on pages 2 and 3.

Before administration of the vaccine, please click to see

Fact Sheets and Prescribing Information for individuals 12 years of age and older

- **Full Prescribing Information (16 years of age and older)**
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
- **Recipients and Caregivers Fact Sheet (12 years of age and older)**

Fact Sheets for individuals 5 through 11 years of age

- EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- **Recipients and Caregivers Fact Sheet (5 through 11 years of age)**

Emergency Use Authorization

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Important Safety Information and Indication & Authorized Use

Important Safety Information

Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

Primary Series Adverse Events:
In clinical studies (30 mcg modRNA) of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies (30 mcg modRNA) of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study (30 mcg modRNA) of adolescents 12 through 15 years of age, adverse reactions following the administration of the primary series included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of any primary series dose included pain at the injection site (84.3%), fatigue (51.7%), headache (38.2%), injection site redness (26.4%), injection site swelling (20.4%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%).

Booster Dose Adverse Events:
In a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%).

Continued on next page.

Please see Important Safety Information and Indication & Authorized Use on pages 2 and 3.
Before administration of the vaccine, please click to see
Fact Sheets and Prescribing Information for individuals 12 years of age and older
Full Prescribing Information (16 years of age and older)
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
Recipients and Caregivers Fact Sheet (12 years of age and older)
Fact Sheets for individuals 5 through 11 years of age
EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
Recipients and Caregivers Fact Sheet (5 through 11 years of age)

Important Safety Information and Indication & Authorized Use (cont'd)

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the 2 EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

COMIRNATY® (COVID-19 Vaccine, mRNA) and the 2 formulations of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

Indication

COMIRNATY® is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Authorized Use

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 5 years of age and older to provide:

- a 10 mcg modRNA 2-dose primary series to individuals 5 through 11 years of age
- a 30 mcg modRNA 2-dose primary series to individuals 12 years of age and older
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination

COMIRNATY® (COVID-19 Vaccine, mRNA) is authorized for emergency use to provide:

- a 30 mcg modRNA 2-dose primary series to individuals 12 through 15 years of age
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination

Please see Important Safety Information and Indication & Authorized Use on pages 2 and 3.

Before administration of the vaccine, please click to see

Fact Sheets and Prescribing Information for individuals 12 years of age and older

Full Prescribing Information (16 years of age and older)

EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap

EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap

Recipients and Caregivers Fact Sheet (12 years of age and older)

Fact Sheets for individuals 5 through 11 years of age

EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap

Recipients and Caregivers Fact Sheet (5 through 11 years of age)

Find additional resources about the vaccine at www.cvdvaccine-us.com

References: **1**. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; 2021. **2**. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DILUTE BEFORE USE, Purple Cap. Pfizer and BioNTech; December 9, 2021. **3**. Pfizer and BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; December 9, 2021. **4**. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap. Pfizer and BioNTech; October 29, 2021.

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
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New York, NY 10017

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.