IMMUNIZATION COVID-19 UPDATE

ISSUE NO 29 | AUGUST 25, 2021

QUESTION OF THE WEEK:

What is the Office of Public Health doing to create access for and promote monoclonal antibody treatment?

The Office of Public Health is working to expand access to monoclonal antibody (mAb) treatments and alert residents to this therapy. This effort started last year following authorization by the FDA for emergency use of the treatment.

Monoclonal antibodies are man-made antibodies produced in a laboratory that can mimic the human immune system's response to infection. Currently, there are three different mAbs. One is made by Eli Lilly, Bamlanivimab, and Regeneron has developed Casirivimab and Imdevimab. All three have been authorized by the FDA for emergency use for patients age 12 and older.

For patients seeking this treatment, a referral from their doctor is needed. To be suitable for treatment, patients must have mild to moderate COVID-19 symptoms and not be hospitalized. Also, patients must meet the following:

- Have a positive test for SARS-CoV-2 (molecular/PCR or antigen)
- Are within 10 days of the start of their symptoms
- Are at least 12 years of age or older and weigh at least 88 pounds (40 kilograms)
- Are at high risk for progressing to severe COVID-19 and/or hospitalization

There are now hospitals and other sites throughout Louisiana that offer mAb treatment, and OPH is working to expand the number of sites.

To view an interactive national map that shows locations that have received shipments of monoclonal antibody therapeutics, visit protect-public.hhs.gov.

VACCINE DOSES ADMINISTERED IN LOUISIANA

3,974,678*

***1,873,834 people fully vaccinated**

FDA FULLY APPROVES FIRST COVID-19 VACCINE

The FDA has approved the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 disease. (Page 2)

LICENSED LONG-TERM CARE FACILITIES REQUIRED TO PLAN FOR COVID-19 BOOSTER DOSES

LDH is asking LCTFs to select a plan to administer booster doses to residents and staff, then complete a survey by Friday, August 27 to let LDH know of their decision. (Page 3)

WEEKLY COVID-19 VACCINE UPDATE

Here is an overview of major updates that occurred over the week.

FDA Fully Approves First COVID-19 Vaccine

The U.S. Food and Drug Administration (FDA) approved the first COVID-19 vaccine, known ad the Pfizer-BioNTech COVID-19 Vaccine (now marketed as Comirnaty) for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA) for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety, and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval.

Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older.

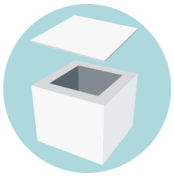
Based on the results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease.

For more information on the FDA approval of Comirnaty, visit fda.gov.

Johnson & Johnson Vaccine Available for Ordering

Johnson & Johnson (Janssen/ J&J) COVID-19 vaccine is once again available for provider ordering. *Please note: the available quantities of the J&J vaccine might be limited, so large order requests may have quantities reduced by the Immunization Program.*

Pfizer Minimum Direct Shipment Size Increased



The minimum available Pfizer COVID-19 vaccine orders configuration for a direct shipment from the manufacturer is now back to 1,170 doses, from the previous configuration of 450 doses. The 1,170-dose shipment from Pfizer will include a single tray that holds 195 vials. This does not apply to smaller orders placed in the LINKS system. Smaller doses will ship from Morris & Dickson and can continue to be ordered in as few as six doses (1 vial).

A few reminders related to the direct shipment from Pfizer:

- Pfizer shipments are delivered ultra-cold at -70°C (-94°F)
- May be stored in the ULT freezer until the expiration date, or temporary in the shipper with regular dry ice replenishment
- May remain frozen at -20°C (-4°F) for up to two weeks
- Undiluted vaccine vials may remain refrigerated for up to one month
- Total storage time in the freezer and refrigerator should not exceed 45 days

If you need any assistance with ordering, email La.Links@La.gov or contact your regional immunization consultant listed on the homepage of LaLinks.org.

Extension of Pfizer Vaccine Shelf Life

The FDA has authorized an extension of the shelf life for the Pfizer COVID-19 vaccine from six months to nine months (an additional three months).

Cartons and vials of Pfizer COVID-19 vaccine with an expiration date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as authorized storage conditions are between -90 to -60°C (-130 to -76°F) have been maintained (ultra-low temperature freezer storage). Please note: Frozen vials stored at -25 to -15°C (-13 to 5°F) and refrigerated vials stored at 2 to 8°C (36 to 46°F) are NOT eligible for extension.

The Immunization Program will automatically update the Pfizer expirations dates in LINKS to reflect this new extended expiration date. **No additional provider action is required related to the updating of expiration dates within LINKS.** Providers should adjust their own internal system records or any other physical documentation of expirations dates, as needed.

For more information on the shelf life extension for the Pfizer COVID-19 vaccines, visit fda.gov.

Licensed Long-Term Care Facilities Required to Plan for On-site Third Dose COVID-19 Vaccine Administration

The Centers for Disease Control (CDC) is expected to recommend a third booster dose of COVID-19 mRNA vaccine for residents and staff at long-term care facilities (LTCFs) eight months after completing a previous two-dose series. The Louisiana Department of Health (LDH) is committed to ensuring all licensed LTFCs in the state have access to vaccines and have a firm **plan for timely on-site vaccination services to administer the third dose.**

Licensed LTCFs can select from the following options for on-site administration of the third-dose COVID-19 vaccines:

- **Partner directly with a pharmacy** that is enrolled in a federal or state COVID-19 vaccination program. *Make sure to confirm with the pharmacy that they are available and willing to provide on-site booster vaccines.*
- **Request that the Louisiana Independent Pharmacies Association (LIPA) coordinate with a local vaccine provider** or vaccination team to provide on-site vaccination clinics.
- **Enroll directly as a COVID-19 vaccine provider** with the Louisiana COVID-19 Vaccination Program to order and administer vaccines accordingly.

Once you have decided on a plan, complete a short online survey to indicate which option you have chosen. Click **HERE** to access the survey. **The survey must be completed by close of business, Friday, August 27, 2021**.

Facilities that DO NOT respond to the survey by the due date will default to having LIPA coordinate third-dose on-site vaccination services.

For more information on third-dose booster vaccine planning, visit ldh.la.gov.

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LOUISIANA COVID-19 VACCINE DEMOGRAPHICS

SERIES COMPLETED BY RACE:

- **White:** 58.13%
- **Black:** 29.67%
- **American Indian:** 0.36%
- **Asian:** 2.96%
- **Native Hawaiian:** 0.21%
- **Unknown:** 1.666%
- **Other:** 7.02%

SERIES COMPLETED BY AGE:

- **5-17:** 3.88%
- **18-29:** 11.08%
- **30-39:** 12.23%
- **40-49:** 13.38%
- **50-59:** 17.44%
- **60-69:** 20.88%
- **70+:** 21.09%

SERIES COMPLETED BY GENDER:

- **Female:** 54.58%
- **Male:** 45.15%
- **Unknown:** 0.27%

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

New Orleans tourism industry worries as coronavirus rages – This article talks about how tourism is being affected by the pandemic, affecting bars and restaurants in New Orleans.

Read more at apnews.com.

COVID is worse than ever. But Louisiana isn't shutting down like it did before. Here's why – This article talks about why Louisiana is not reinstating the capacity limits and curfews like the last surge.

Read more at theadvocate.com.

COVID-19 shuts campuses down, thousands more sent home for 14-day quarantine 1 week into the school year – This article talks about how a week after schools open, Terrebonne and Lafourche parish school districts were forced to quarantine over 2,000 students and staff.

Read more at wdsu.com.