LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-26: Update for Clinicians on Testing and Treatment for Monkeypox**
Origination Date: *August 1, 2022*	**Revision Dates (List All Revision Dates):**

Update for Clinicians on Testing and Treatment for Monkeypox

Summary
As of July 28, 2022, the Centers for Disease Control and Prevention (CDC) and state and local public health partners are reporting 5,189 cases of monkeypox in the United States across 47 states, Washington, D.C., and Puerto Rico. Globally, 22,141 monkeypox cases have been identified across 72 countries that normally do not report monkeypox. In Louisiana, 49 monkeypox cases have been detected as of August 1, 2022. Monkeypox cases in Louisiana have been identified across 4 of the 9 Louisiana Department of Health (LDH) regions.

This Health Alert Network (HAN) Health Update serves to alert clinicians on commercial testing capability, collecting clinical specimens for testing, using TPOXX® (tecovirimat) for treating monkeypox, and vaccine eligibility and availability in Louisiana.

Recommendations for Healthcare Providers on Diagnostic Testing
Healthcare providers in Louisiana should be on alert for patients who have rash illnesses consistent with monkeypox. Distinguishing features of the rash include papules, vesicles, pustules, or scabs that are deep-seated, firm or rubbery, and have well-defined round borders. Vesicular or pustular stages of the lesions are often umbilicated (i.e., have a dent in the middle of them). They may be painful, painless, or itchy. People with monkeypox may develop symptoms including fever, headache, muscle aches, exhaustion or swollen lymph nodes during the prodromal period preceding the rash or with the rash.

The public health response to monkeypox depends on timely and comprehensive laboratory testing and reporting of those results. Tests should be performed on persons for whom monkeypox is suspected based on clinical presentation and epidemiologic criteria. Positive diagnostic results from testing of skin lesion material for *Orthopoxvirus* or *Monkeypox virus* DNA in persons without epidemiologic criteria or known risk factors should be verified through repeat testing and/or confirmatory testing.

If there are no identified epidemiologic risk criteria for monkeypox infection, other possible causes of rash in adults should be considered, including secondary syphilis, herpes, and varicella zoster. In children without identified epidemiologic risk criteria for monkeypox, varicella zoster and molluscum contagiosum (MC) should be considered in the differential diagnosis. MC is an infection caused by a poxvirus (molluscum contagiosum virus) that is diagnosed more often in children than in adults. MC infection is usually a benign, mild skin disease characterized by lesions that may appear anywhere on the body. CDC's FDA-cleared non-variola virus test used within the Laboratory Response Network laboratories and most

commercial laboratories, does not cross-react with molluscum contagiosum virus. In children and adolescents, as in adults, other potential etiologies of illness should be tested for in parallel with or before *Monkeypox virus* testing, based on clinical presentation and epidemiologic criteria.

Specimen Type and Collection

1. The recommended specimen type is material collected from the surface of a lesion or crust from a healing lesion. CDC recommends that three lesions per patient be swabbed. Swab the surface of the lesion vigorously to collect adequate DNA. It is not necessary to de-roof or lance the lesion before swabbing. For some individuals, the lesions may not be overtly visible (such as within the oral cavity or within the rectum), therefore clinicians should perform a thorough evaluation including a full body skin, oral, genital, and rectal examination to identify appropriate lesions for sampling.
2. Different laboratories may vary in their specimen preparation requirements. Please contact the appropriate public health department or commercial laboratory to determine acceptable specimens.

Testing Capacity and Costs

To build upon CDC's and the Laboratory Response Network's testing capacity, CDC recently worked to bring testing online at five commercial laboratory companies. All five commercial laboratories are now online and, combined with the CDC's Laboratory Response Network, have increased national *Monkeypox virus* testing capacity from 6,000 to up to 80,000 specimens per week.† It is not necessary to first consult with state or federal health officials prior to initiating diagnostic testing at commercial laboratories.

Non-variola orthopoxvirus testing continues to be available through the State Public Health Laboratory (SPHL). Providers requesting testing through the SPHL should call the Infectious Disease Epidemiology (IDEpi) 24/7 clinician hotline (800-256-2748) for specimen collection instructions and courier transport.

Orthopoxvirus Results Interpretation

Once results are received from the laboratory, a positive *Orthopoxvirus* test is considered to meet the case definition for probable *Monkeypox virus* infection since there are no other circulating *Orthopoxviruses* within the United States that cause systemic disease. Clinical care and prevention precautions should begin based on the *Orthopoxvirus* test result and should not wait for any additional viral characterization testing that may be performed.

Information for Healthcare Providers on Tecovirimat Treatment

Tecovirimat (also known as TPOXX or ST-246) is approved by the Food and Drug Administration (FDA) for treating human smallpox disease caused by *Variola virus* in adults and children. Its use for other *Orthopoxvirus* infections, including monkeypox, is not approved by the FDA. However, CDC has an expanded access Investigational New Drug application (EA-IND) to allow access to and use of TPOXX to treat monkeypox in adults and children of all ages.

The EA-IND provides an umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs. The EA-IND also provides liability protection under the PREP Act for healthcare providers prescribing, administering, or dispending the drug, and ability for patients to seek compensation if they are seriously injured by the medication through the Countermeasures Injury Compensation Program (CICP). In the largest safety study of 359 healthy adult volunteers, other than local site reactions the most common adverse reactions among those receiving tecovirimat were headache (12%) and nausea (5%) [LABEL (fda.gov)]. The safety of tecovirimat has not yet been studied in people with *Orthopoxvirus*

Treatment Consideration
Tecovirimat may be considered for treatment in people infected with *Monkeypox virus*:

- With severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- Who are at high risk of severe disease
- With aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where *Monkeypox virus* infection might constitute a special hazard (e.g., the genitals or anus)

How to Obtain Tecovirimat (TPOXX)

- TPOXX is available through the Strategic National Stockpile, and LDH has pre-positioned supplies of TPOXX within their Louisiana. All clinicians and care facility pharmacists requesting TPOXX should contact the **IDEpi clinician 24/7 hotline: 800-256-2748.**
- Treatment with TPOXX can begin upon receiving the medication and after obtaining informed consent. No pre-registration is required for clinicians or facilities to begin treatment.
- Forms requested under the EA-IND can all be returned to CDC **after** treatment begins.

TPOXX Expanded Access Investigational New Drug Protocol (**IND 116,039/Protocol 6402)**
CDC, in partnership with FDA, has made it easier for healthcare providers to provide tecovirimat (TPOXX) treatment to patients with monkeypox under the EA-IND protocol. The streamlined process reduces the number of required patient treatment forms from six (21 pages) to two (7 pages); decreases patient visits to three visits that can all be conducted via telemedicine; and makes collecting blood, lesion samples, and lesion photos optional. Additional information about the EA-IND protocol for TPOXX can be found here.

It is important to note that clinicians can start the patient's treatment upon obtaining informed consent. All forms can be completed and submitted after treatment initiation to facilitate timely care of the patient. Timely return of patient intake and clinical outcome forms by providers and healthcare facilities enables CDC to monitor clinically appropriate and safe use of TPOXX.

Information for Providers on Jynneos Vaccine
The FDA has licensed JYNNEOSTM (also known by the brand names Imvamune and Imvanex), a replication-deficient smallpox vaccine, for the prevention of smallpox and monkeypox. JYNNEOSTM is an attenuated live virus vaccine. As a replication-deficient vaccine, it can be used for vaccination of people 18 years and older with certain immune

deficiencies or conditions, such as HIV or atopic dermatitis. JYNNEOSTM has been studied in people with HIV and atopic dermatitis and no severe adverse events were identified.

LDH has ordered all available JYNNEOSTM doses that have been allocated to Louisiana by CDC. These vaccines are being distributed to regional offices of public health and a limited number of partner providers. Because doses remain in limited supply, LDH is prioritizing JYNNEOSTM vaccine for 2 purposes:

- **Post-Exposure Prophylaxis (PEP):** Vaccination following a known exposure to monkeypox to help prevent illness from monkeypox virus
- **Expanded Post-Exposure Prophylaxis (PEP)++:** Vaccination of individuals who are more likely to have been recently exposed to monkeypox

Individuals who are eligible for PEP are identified by LDH epidemiologists during case investigation. These individuals will be contacted by public health staff and referred to parish health units for PEP vaccination.

The supply of vaccine allocated to LDH is not abundant enough to immediately vaccinate all those who may benefit from vaccination with JYNNEOSTM. As a result, PEP++ vaccine doses will be prioritized according to the greatest risk for exposure. Eligibility groups will expand as the vaccine increases. At this time, the following groups are eligible for PEP++ vaccine in Louisiana:

- Gay, bisexual, or other (cis or trans) men who have sex with men **AND**
    - Have had intimate or sexual contact with multiple or anonymous partners in the last 14 days **OR**
    - Have given or received money or other goods/services in exchange for sex in the last 14 days **OR**
    - Have had intimate or sexual contact with other men in a social or sexual venue in the last 14 days

Locations that are administering PEP++ vaccines (based on availability) can be found here.

Update for Clinicians on Monkeypox in People with HIV, Children and Adolescents, and People who are Pregnant or Breastfeeding

CDC recently issued clinical considerations for monkeypox infection in multiple populations including: people with HIV, children and adolescents, and people who are pregnant or breastfeeding. These newly released clinical considerations complement existing clinical guidance for managing monkeypox and provide information on signs and symptoms of *Monkeypox virus* infection; pre- and post-exposure prophylaxis; treatment; and infection control in these populations. The update CDC released through the health alert network can be found here.

For More Information

- Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC
- How to Report Test Results
- Preparation and Collection of Specimens

- Obtaining and Using TPOXX (Tecovirimat)
- Treatment Information for Healthcare Professionals | Monkeypox | Poxvirus | CDC
- Visit CDC-INFO or call CDC-INFO at 1-800-232-4636
- CDC 24/7 Emergency Operations Center (EOC) 770-488-7100

Footnote

†Testing at public health laboratories remains free. Commercial laboratory companies will bill private insurance, Medicaid or Medicare for all testing performed. Those who are underinsured or uninsured will receive a bill for that testing. The Administration continues to work to identify funding that would cover the cost of monkeypox testing regardless of the individual's coverage. Clinicians may find the relevant CPT code for Monkeypox virus testing on each commercial laboratory's website.