



Indiana
Department
of
Health

MONKEYPOX

PROVIDER WEBINAR

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Monkeypox Outbreak



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Monkeypox website

- [Monkeypox.health.in.gov](https://monkeypox.health.in.gov)
- Section for the public and clinicians
- Watch here for updates

Information for Clinicians

[Clinical Guide for Monkeypox Testing](#)

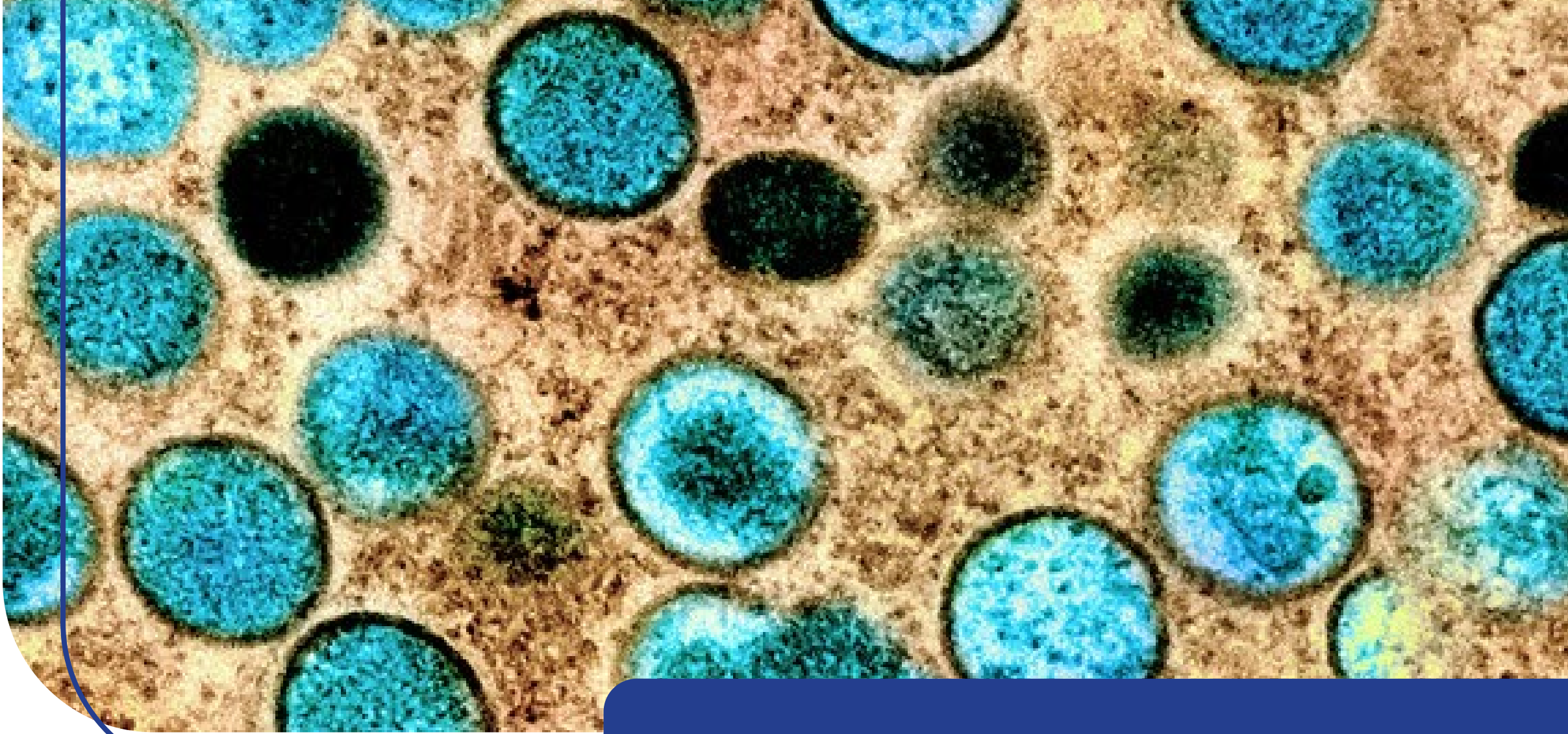
[Frequently-asked Questions](#)

[How do patients present with monkeypox?](#)

[How do I collect and submit specimens?](#)

Demographics of Monkeypox cases in Indiana

- We have had cases in men, women and children:
 - 20% women
 - 12 different counties
- We have had cases from all over the state- not limited to 1 or 2 cities
 - Working on a dashboard to display locations and demographic information
- Majority of cases have been in MSM but not all so please consider in anyone presenting with a concerning rash



Testing



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Who should be tested?

- Patients with a [new characteristic rash typical of monkeypox](#) (deep-seated and well-circumscribed lesions, often with central umbilication; and lesion progression through specific sequential stages—macules, papules, vesicles, pustules, and scabs) **OR**
- Patients for whom there is high clinical suspicion of monkeypox and who within 21 days of illness onset:
 - Had contact with someone who had a rash that looks like monkeypox or someone who was diagnosed with confirmed or probable monkeypox; OR
 - Had skin-to-skin contact with someone in a social network experiencing monkeypox activity; OR
 - Traveled outside the United States to a country with confirmed cases of monkeypox or where monkeypox activity has been ongoing; OR
 - Had contact with a dead or live wild animal or exotic pet that exists only in Africa or used a product derived from such animals (e.g., game meat, creams, lotions, powders, etc.).

How do I test for monkeypox?

- Several commercial labs are now testing for orthopox virus, which detects monkeypox.
- **Please work with your lab staff to send specimens to these commercial labs: Aegis Science, Labcorp, Mayo Clinic Laboratories, Quest Diagnostics and Sonic Healthcare.** Results will be transmitted to the IDOH. Prior IDOH authorization is not required to submit specimens to commercial laboratories.
- If you do not have a contact with one of these five labs, specimens may be submitted through the IDOH Laboratories (IDOHL). First complete the Indiana Department of Health (IDOH) [Monkeypox Specimen Authorization Request form](#).
- Specimens tested through IDOHL should be submitted via [LimsNet](#), an online system that will make results available as PDF files the minute they are released at the lab. [Most hospital labs already have access to LimsNet](#), but if LimsNet access is needed, contact the LimsNet help desk at (317) 921-5506 or email LimsAppSupport@isdh.in.gov.

Quarantine and Isolation

- Patients should be advised to isolate while awaiting results of monkeypox testing. Patients who do not need to be hospitalized may isolate at home but should take precautions to avoid exposure to other people or animals in the household.
- Alternate isolation arrangements may be considered for people with household contacts who could be at increased risk for severe illness due to monkeypox.
- Please refer patients to CDC guidance for home isolation for detailed instructions on how to prevent spread within the household.
- Patients with monkeypox are considered contagious from the onset of **any** symptoms (including prodromal symptoms before appearance of rash) until all lesions have crusted, the crusts have separated, and a new layer of skin has formed underneath. This usually takes 2-4 weeks but may take longer in some individuals.

NDC 50632-001-02

Smallpox and Monkeypox Vaccine, Live, Non-replicating

JYNNEOS®

Suspension for subcutaneous injection



Contains 20 single-dose 0.5 mL vials

BAVARIAN NO

Vaccination



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Vaccine Effectiveness

- Because monkeypox virus is closely related to the virus that causes smallpox, the smallpox vaccine can protect people from getting monkeypox.
- Past data from Africa suggests that the smallpox vaccine is at least 85% effective in preventing monkeypox.
- The effectiveness of JYNNEOSTM against monkeypox was concluded from a clinical study on the immunogenicity of JYNNEOS and efficacy data from animal studies.
- No data are available yet on the effectiveness of these vaccines in the current outbreak.
- Smallpox and monkeypox vaccines are effective at protecting people against monkeypox when given before exposure to monkeypox. Experts also believe that vaccination after a monkeypox exposure may help prevent the disease or make it less severe.

Vaccine Allocation

- We have received 3226 doses of Jynneos vaccine (enough for 1600 people) and have given 57 first doses
- Unsure when we will receive our next allocation or how much we will receive
- Expected to use the vaccine primarily for PEP and laboratory workers who will be testing for orthopox

Who should get vaccinated?

- People who have had a [high- or intermediate-risk exposure](#) to someone with monkeypox may be vaccinated. [ACAM2000](#) and [JYNNEOS](#) are the two licensed vaccines in the United States to prevent smallpox and may be given as post-exposure prophylaxis for monkeypox.
- [CDC guidance](#) indicates that if given within 4 days of exposure, these vaccines may prevent monkeypox. If given 4-14 days after exposure, the vaccines may reduce symptoms, but may not prevent monkeypox.
- CDC does **not** currently recommend routine pre-exposure vaccination for most U.S. healthcare workers.
- Recommendations for routine pre-exposure vaccination are generally limited to clinical laboratory personnel who routinely handle orthopoxviruses and individuals designated by public health authorities to be vaccinated for preparedness purposes.

Preparation and administration

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered
- Swirl the vial gently before use for at least 30 seconds. Withdraw a dose of 0.5 mL into a sterile syringe for injection
- If the patient is <18 years, the Indiana Department of Health (IDOH) will have to coordinate with CDC Regulatory Affairs for administration of JYNNEOS under CDC's investigational new drug (IND) protocol for administration. IDOH will coordinate with the provider and CDC directly for these requests.

Adverse events

- Across all three studies, solicited local adverse reactions reported following any dose of JYNNEOS were
 - redness (80.9%), pain (79.5%), induration (70.4%), swelling (67.2%), and itching (32.0%) at the injection site;
- Solicited systemic adverse reactions reported following any dose of JYNNEOS were
 - fatigue (33.5%), headache (27.6%), muscle pain (21.5%), nausea (9.8%), chills (0.7%), and fever (0.5%).
- Potential Serious Adverse Event: Major cardiac risk factors include hypertension, diabetes, hypercholesterolemia, heart disease at age 50 years in a first degree relative, and smoking
- Clinical studies have not detected an increased risk of myopericarditis in recipients of JYNNEOS
- Persons with underlying heart disease or ≥ 3 major cardiac risk factors should be counseled on the theoretical risk of myopericarditis given the uncertain etiology of myopericarditis associated with replication-competent smallpox vaccine

Vaccine administration frequency

- Two doses of JYNNEOS (0.5 mL each)
- Subcutaneous injection four weeks apart
- People are considered fully vaccinated about two weeks after their second shot of JYNNEOS
- People who get vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox

Storage and handling

- Keep frozen at -25°C to -15°C (-13°F to $+5^{\circ}\text{F}$)
- Once thawed, the vaccine may be refrigerated at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ ($+36^{\circ}\text{F}$ to $+46^{\circ}\text{F}$) for 8 weeks.
- Store in the original package of 20 single-dose vials to protect from light
- Do not re-freeze a vial once it has been thawed
- Allow the vaccine to thaw and reach room temperature before administration
- When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension
- Do not use the vaccine after the expiration date shown on the vial label, but don't discard doses, and continue to properly store, as expiry may be extended.

Post-exposure Prophylaxis (PEP)

- The [Centers for Disease Control and Prevention \(CDC\) recommends](#) post-exposure prophylaxis for high or intermediate risk contacts of monkeypox cases.
- JYNNEOS (also known as Imvamune or Imvanex) is licensed by the U.S. Food and Drug Administration (FDA) for preventing monkeypox infection. The sooner an exposed person gets the vaccine, the better. CDC recommends that the vaccine be given within 4 days from the date of exposure to prevent onset of the disease. If given 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease but may not prevent the disease.
- There is a limited supply of JYNNEOS, although more is expected in coming weeks and months. **Please submit a [PEP request form](#) to order JYNNEOS for patients who have been exposed to a confirmed case.**

PEP Request Form

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JYNNEOS Vaccine Post-Exposure Prophylaxis (PEP) Request

Please complete the following REDCap survey to document your request for JYNNEOS vaccine for Monkeypox Post-Exposure Prophylaxis (PEP).

This request form is to be utilized by providers or local health departments (LHDs) only. Patients should contact their provider or LHD to inquire about obtaining JYNNEOS.

CDC recommends PEP for high or intermediate risk contacts of monkeypox cases.
<https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html>.



<https://redcap.isdh.in.gov/surveys/?s=P4JAXMXNEC8P473F>

Pre-Exposure Prophylaxis (PrEP)

- IDOH had consulted their statewide vaccine allocation committee about the equitable and ethical distribution of the Jynneos vaccine.
- Indiana has only been allocated a small amount meant to be used primarily to treat people who have been a close contact of a case to prevent severe disease.
- IDOH has begun to vaccinate people who are at high risk for severe illness and high risk for exposure with the limited remaining vaccine and has been contacting those patients directly.
- When the state is allocated more vaccine, we will expand vaccine eligibility to groups at high risk for exposure.
- Please continue to monitor monkeypox.health.in.gov for updates.

Monkeypox and COVID-19 Vaccine

- People who receive an orthopoxvirus vaccine (ACAM2000 or JYNNEOS) might consider waiting 4 weeks after their orthopoxvirus vaccination before receiving a COVID-19 vaccination (Moderna, Novavax or Pfizer-BioNTech) due to the small risk of myocarditis after receipt of ACAM2000 and the unknown risk of myocarditis after receipt of JYNNEOS.
- However, if orthopoxvirus vaccination is needed to help prevent infection in an outbreak, orthopoxvirus vaccination should NOT be delayed because of recent receipt of a COVID-19 vaccine (Moderna, Novavax or Pfizer-BioNTech).
- There is no required minimum interval between COVID-19 vaccination and orthopoxvirus vaccination.

Revaccination After Exposure

- Persons exposed to monkeypox virus and who have not received the smallpox vaccine within the last 3 years, should consider getting vaccinated.
- The sooner the person receives the vaccine, the more effective it will be in protecting against monkeypox virus.

Additional Vaccine Resources

- [JYNNEOS vaccine information statement \(VIS\)](#) should be provided to all vaccine recipients
- [JYNNEOS package insert](#)
- General CDC [information on smallpox vaccination](#)
- ACIP [guidance](#) on use of JYNNEOS vaccine



Treatment



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TPOXX (tecovirimat)

- Many people infected with monkeypox virus have a mild, self-limiting disease course in the absence of specific therapy.
- The prognosis for monkeypox depends on multiple factors, such as previous vaccination status, initial health status, concurrent illnesses, and comorbidities, among others. Please refer to CDC guidance regarding [indications for monkeypox treatment](#).
- [Tecovirimat](#) (also known as TPOXX, ST-246) is available for the treatment of monkeypox under an investigational new drug (IND) protocol sponsored by the CDC.
- Other treatment options are less commonly used but may include Vaccinia Immune Globulin Intravenous (VIGIV), Cidofovir (also known as Vistide), or Brincidofovir (also known as CMX001 or Tembexa). More information on treatment options is available [here](#).

How do I order TPOXX?

- For patients with probable or confirmed monkeypox
- Tecovirimat (also known as TPOXX or ST-246) is FDA-approved for the treatment of human smallpox disease caused by *Variola virus* in adults and children.
- However, its use for other orthopoxvirus infections, including monkeypox, is not approved by the FDA.
- CDC holds a non-research expanded access Investigational New Drug (EA-IND) protocol that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children of all ages.
- **This request form is to be utilized by providers or local health departments (LHDs) only.** Patients should contact their providers to inquire about obtaining TPOXX for treatment.
- A unique survey entry must be completed for each individual TPOXX request.



TPOXX Request Form



TPOXX (Tecovirimat) Request Survey

Please complete the below REDCap survey to request TPOXX (tecovirimat). ***A unique survey entry must be completed for each individual TPOXX request.***

This request form is to be utilized by providers or local health departments (LHDs) only. Patients should contact their providers to inquire about obtaining TPOXX for treatment.

Tecovirimat (also known as TPOXX or ST-246) is FDA-approved for the treatment of human smallpox disease caused by *Variola virus* in adults and children. However, its use for other orthopoxvirus infections, including monkeypox, is not approved by the FDA. Therefore, CDC holds a non-research expanded access Investigational New Drug (EA-IND) protocol that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children of all ages.

[Interim Clinical Guidance for the Treatment of Monkeypox](#)

[Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases](#)

Upon receipt of request, IDOH will review your request.



<https://redcap.isdh.in.gov/surveys/?s=3REN7J3XRDE3FTTJ>

TPOXX Oversight Reporting

It is the responsibility of the clinician providing oversight to complete the below paperwork and submit to the CDC based on the reporting links below. (all linked on the request form)

[Tecovirimat IND Protocol CDC IRB](#)

[Tecovirimat IND Form FDA 1572](#)

Required

- Informed consent (Page 47 of PDF) - **obtained prior to treatment initiation.**
- FDA Form 1572 - To be completed by the responsible clinician/healthcare provider overseeing the patient's treatment. Please return **within 3 calendar days** of tecovirimat treatment initiation along with a CV of the treating physician.
- Patient intake form to provide patient's baseline condition at the time of tecovirimat treatment decision. Complete the sections/fields that are applicable to the patient. For clinical labs (e.g., CBC with differential, UA, metabolic panel) performed at baseline, please include a copy of the results. Please return **within 3 calendar days** of tecovirimat treatment to the extent possible.

TPOXX Oversight Reporting

Required cont'd

Adverse event form (Page 62 of PDF) to report whether any adverse event(s) occurred during treatment with tecovirimat. Return to CDC at the end of patient's tecovirimat treatment course. Life-threatening or serious adverse events during tecovirimat therapy should be reported to CDC by completing the adverse event form and returning it to regaffairs@cdc.gov **within 24 hours** of occurrence or as soon as possible.

- 1 Outpatient Case Report Form (Attachment 2B-Form D in the IND protocol) during tecovirimat therapy (e.g., Day 7) to provide clinical progress of the patient. If clinical labs (e.g., CBC with differential, UA, metabolic panel) can be performed during treatment, please include a copy of the results. Return **within 3 calendar days** of patient follow-up.
- 1 Post Tecovirimat Treatment Form (Attachment 2B-Form E in the IND protocol) to provide patient's clinical outcomes information after completion of treatment. If clinical labs (e.g., CBC with differential, UA, metabolic panel) can be performed at the conclusion of treatment, please include a copy of the results. Return **within 3 calendar days** of patient follow-up.

TPOXX Oversight Reporting

Optional

- Photos of lesions: Ideally, a photograph of at least 1 lesion prior to tecovirimat treatment and then the same lesion photographed again during treatment between days 7 and 14 (indicated dates on photos). Provide photo(s) of any new lesions that develop during or up to 7 days after completion of tecovirimat treatment.
- Samples of lesions for molecular testing: Ideally, a sample from at least 1 lesion prior to tecovirimat treatment but only if baseline diagnostic testing wasn't performed, as well as samples from any new lesions that develop during tecovirimat treatment or up to 7 days after completion of tecovirimat treatment for development of antiviral resistance mutations. Submit samples to CDC with CDC Form 50.34, and indicate Poxvirus Molecular Detection (CDC-10515) as the test order (code).

It is the administering provider's responsibility to complete and submit the required documentation. Please return completed IND protocol forms to CDC using one of the following methods:

- Secure Share File for lesion photos and large file sizes (please zip multiple files and use filenames with patient identifier, hospital name, and date): <https://centersfordiseasecontrol.sharefile.com/r-r3941801ebcbd4002b4dfe98e314ec697>
- Email: regaffairs@cdc.gov
- Fax: 404-902-5921

Questions?

