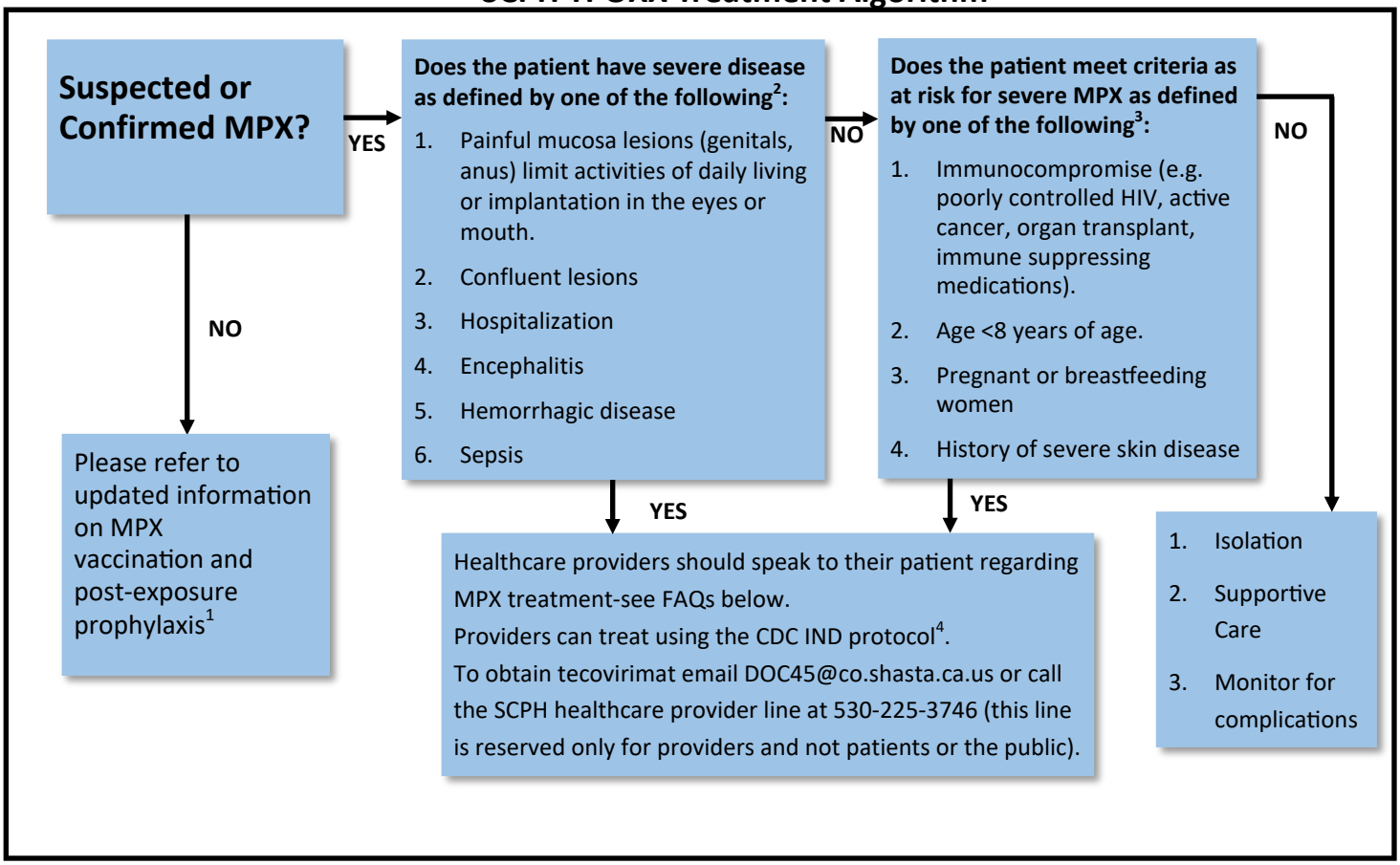
Guidance for the Treatment of MPX-Tecovirimat

Background: The number of reported monkeypox virus (MPX) cases has continued to increase across the United Sates including California. The current circulating strain of MPX has been to date limited to the West African clade, which tends to cause milder disease. Most patients have mild disease and recover without medical intervention. Patients with severe MPX disease or who are at high risk for severe disease should be considered for treatment.

Currently there is no treatment approved specifically for MPX virus infections. However, antivirals developed for use in patients with smallpox may prove beneficial against MPX. The following clinical guidelines and FAQs are to support clinicians obtaining and using tecovirimat. For information on other therapies see CDC MPX Treatment Information. Go to www.ShastaReady.org and click "Medical Professionals" for current local guidance including MPX testing, treatment, vaccination.

Tecovirimat (also known as TPOXX or ST-246) is an FDA-approved antiviral medication for the treatment of human smallpox disease. The CDC holds an expanded access Investigational New Drug (EA-IND) protocol that allows for the use of stockpiled tecovirimat to treat MPX disease during an outbreak. Tecovirimat is available for use in Shasta County for patients who meet the CDC clinical criteria (see SCPH TPOXX Treatment Algorithm below). **Informed consent is required** for all patients treated with tecovirimat. Tecovirimat is available in oral and intravenous formulations. If a provider has a patient in urgent need of treatment, the provider may proceed with tecovirimat treatment once informed consent has been obtained. **Paperwork does not need to be completed to initiate treatment.**

SCPH TPOXX Treatment Algorithm[1]



Algorithm footnotes

1 Adapted from CDC Interim clinical guidance for treatment of MPX; adapted from LAC DPH guidance for treatment of MPX-Tecovirimat

2 See www.ShastaReady.org and click "Medical Professionals" for the most current vaccination recommendations.

3 Please refer to CDC treatment considerations for tecovirimat. Patient selection for treatment is at the discretion of the treating clinician under the EA-IND.

4 CDC IND protocol information

Shasta County Health & Human Services Agency

Shasta County Public Health
www.ShastaReady.org
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Obtaining Tecovirimat

Data are not available on the effectiveness of tecovirimat in treating MPX infections in people, but studies using a variety of animal species have shown that tecovirimat is effective in treating disease caused by orthopoxviruses. Clinical trials in people showed the drug was safe and had only minor side effects.

Providers can contact the Shasta County Public Health via email DOC45@co.shasta.ca.us to obtain tecovirimat the necessary documentation. Providers can begin treatment following the CDC IND protocol forms (emailed). Providers will need to submit required documents necessary for the IND protocol directly to the CDC. If further orthopoxvirus testing is deemed necessary, at discretion of the treating clinician according to the IND protocol, SCPH can coordinate specimen submission to the CDC.

Providers have the option to initiate this process prior to having an identified patient and request supply to have on hand. To obtain additional information and required forms to start the process, please email DOC45@co.shasta.ca.us

Immediate need – Patient urgently needs Tecovirimat

If a provider has a patient in urgent need of treatment, the provider may proceed with tecovirimat treatment ***once informed consent has been obtained. Paperwork does not need to be completed to initiate treatment.***

The use of tecovirimat for MPX is under the EA-IND which has been CDC IRB-approved and authorized by FDA to proceed. Patient-level approval is not required from FDA in order to initiate treatment (except for pediatric patients, if a pediatric patient is in need of treatment at this time, CDC requires use of a single-patient IND, which would require patient level FDA authorization prior to administration).

To obtain additional information and required forms to start the treatment process, please email DOC45@co.shasta.ca.us or call the SCPH healthcare provider line at 530-225-3746 if you need immediate assistance with the communicable disease team.

Frequently Asked Questions about MPX Treatment with Tecovirimat

What drugs are available in Shasta County for the treatment of MPX?

Tecovirimat (TPOXX) is an investigational new drug available for the treatment of MPX and is available in Shasta County if the patient meets treatment criteria as per CDC clinical guidance. TPOXX is an antiviral medication available through an expanded access Investigational New Drug (EA-IND) protocol for the treatment of MPX infection. Informed consent is required for all patients treated with tecovirimat. Tecovirimat is available in oral and intravenous formulations. Other drugs (brincidofovir, vaccinia immune globulin) are potentially available, but are considered second-line drugs.

How effective is tecovirimat for the treatment of MPX?

Experience with and data for tecovirimat treatment for MPX is currently very limited. Animal studies suggest mortality benefit. The oral drug has been well tolerated in the people who have received it this far and appears to be effective in laboratory studies, but the drug is still considered an investigational new drug. Safety and side effects have not been studied in pregnancy, breastfeeding, and pediatrics.

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What can my patient expect if they start treatment with tecovirimat?

Standard adult oral dosing of tecovirimat is 600mg every 12 hours for 14 days. For most adults, this will require taking 3 pills every 12 hours. Tecovirimat capsules should be taken within 30 minutes after a full meal containing moderate or high fat. Co-administration of the diabetes drug repaglinide may increase the risk of hypoglycemia. IV formulations are available for the drug if needed for hospitalized patients.

Patients who start tecovirimat need to consent for use of an investigational new drug and will need to follow-up with their provider according to the CDC's EA-IND protocol which may include blood tests if the patient's clinical condition necessitates performing clinical labs. Required and optional items for healthcare providers using TPOXX following CDC's EA-IND protocol can be found here.

What are the side effects of tecovirimat?

Tecovirimat is generally well tolerated and side effects were fairly rare and mild. There was a small increase in headache (12%) and nausea (5%) for patients taking tecovirimat as compared to placebo (8% and 4% respectively).

If my patient is not a candidate for pharmacological treatment of MPX, what other treatments are recommended?

Most patients with MPX have mild disease and should recover without medical intervention. Supportive and symptomatic care such as fluids, antipyretics and pain control is recommended. If the patient's MPX disease worsens, they should be re-assessed for tecovirimat therapy.

What are the isolation instructions for patients with MPX?

For individuals with MPX, isolation precautions should be continued until all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed. See CDC MPX infection control in healthcare settings and at home for more details. The California Department of Public Health has also released Monkeypox Home Isolation Guidance for the General Public.

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