INFORMED CONSENT/ PARENTAL PERMISSION FORM FOR TECOVIRIMAT TREATMENT

Please read this consent form carefully and ask any questions you/your child may have. If you want to get tecovirimat under this treatment program, we will ask you to sign this consent form. You will get a copy of this form to keep. The use of "you" in this consent form may not apply for minors or people who, for other reasons (such as serious illness, limited English proficiency), cannot read and/or fully understand the contents. In cases when a person is unable to give consent, the parents or other legal guardians must review the contents of the consent form and give permission for the person to be treated. Verbal translation by an interpreter or a family member or friend who speaks the patient's language may be used to get the consent of the patient with limited English proficiency.

BACKGROUND

You are being offered tecovirimat (Tpoxx) because you:

- Have or may have been exposed to a pox virus (such as monkeypox) and have infection or may be at risk of developing infection, including a serious or life-threatening disease.

OR

- Have or may have been exposed to the virus in the smallpox vaccine called ACAM2000 that contains replicating live virus, contact with another person who got the smallpox vaccine, or some other way, and have developed a serious reaction.

This program is sponsored by the Centers for Disease Control and Prevention (CDC). This form provides information you may want to know about tecovirimat before you decide to take it.

WHAT ARE POXVIRUSES?

Poxviruses are a family of viruses that can cause serious diseases such as smallpox and monkeypox . Poxviruses may cause the following symptoms:

- Severe rash that can leave scars
- when healed
- High fever
- Chills
- Severe headaches
- Backache and/or muscle aches
- Swollen glands in the armpits (lymph nodes)
- Tiredness

The illness typically starts with a fever and other symptoms before the rash begins. However, the rash may begin without other symptoms. The rash looks like raised bumps and pus-filled blisters (called lesions). They usually crust, scab, and fall off after about 2-4 weeks, leaving a pitted scar.

Some people who get the smallpox vaccine ACAM2000 or come in contact with a person who got the vaccine may develop serious reactions such as spread of the vaccinia virus (the virus used in ACAM2000 vaccine) to other parts of the body or serious conditions that may require treatment with tecovirimat.

WHAT IS TECOVIRIMAT?

Tecovirimat (also known as TPOXX or ST-246) is a drug that may help to treat infections caused by pox viruses and reactions to the smallpox vaccine. Tecovirimat is approved by the Food and Drug Administration (FDA) to treat smallpox in adults and children. Tecovirimat is available as capsules (pills). It also comes in a liquid injection form that is given directly into a vein (bloodstream) on your arm or hand through a needle or tube (called an IV infusion). Your doctor will decide if you should be treated with tecovirimat pills or by IV infusion. FDA has reviewed information on tecovirimat and determined that tecovirimat may help treat infection, including serious or potentially life-threatening disease, from poxviruses.

WHAT WILL HAPPEN IF YOU CHOOSE TO BE TREATED WITH TECOVIRIMAT?

- If you agree to tecovirimat treatment, you will need to sign this consent form to begin receiving tecovirimat.
- You will be asked about your health, any medicines that you are taking, and any allergies you have.
- Your doctor will give you the right dose of tecovirimat and explain how to take it and for how long. Tecovirimat is usually given for 14 days. Your treatment may be longer depending on how serious your infection is.
- If taking tecovirimat by mouth, be sure to eat a full, fatty meal 30 minutes before taking tecovirimat and take each dose with a full glass of water. The meal should contain about 600 calories and 25 grams of fat such as cheeseburger with fries, rice with fried chicken, pasta alfredo, bagel with cream cheese, avocado, peanut butter, ready-to-drink meal, etc.
- For children and adults unable to swallow capsules, follow the instructions for "Opening and Mixing Tecovirimat Capsules with Food."
- People who are hospitalized with serious illness and have trouble taking capsules or eating a full meal may be given tecovirimat through an IV.
- Your doctor will give you a diary card for you to fill out to track your illness progress. You will be asked to fill out this diary card and return it to CDC or upload to the ShareFile link on the form.
- Infection with a poxvirus can be a serious illness, so getting treatment may involve some laboratory testing if your doctor thinks it's necessary. This could include getting your blood, urine or samples of rash, if you have rash. If you are willing and it is feasible, some blood may be taken just before and/or after a few doses of tecovirimat during your treatment. This helps to see if the dose taken is appropriate.
- If you have any lesions, pictures of them may be taken throughout your treatment to see if they are getting better. If you are being treated as an outpatient, your doctor may also ask you to take pictures of your lesions send them send to your doctor. Your doctor may send pictures of your lesions to CDC.
- Your doctor will follow up with you after the last dose or when you have gotten better.
- Your contact information may be provided to CDC to invite you to participate in any post-therapy surveys, if conducted.

WHAT ARE THE BENEFITS OF TECOVIRIMAT?

We do not know for certain if you will benefit from tecovirimat. Based on what we know about tecovirimat, the drug may help to treat your infection or vaccine reaction and prevent it from getting worse. The potential benefit of tecovirimat is that it may help to cure your illness.

WHAT ARE THE RISKS OF TECOVIRIMAT?

The risks of tecovirimat in people with smallpox or other poxviruses are not known. Tecovirimat has not been studied in people with weak immune systems, the elderly, or children. Tecovirimat 600 mg capsules were tested in 359 healthy adults, including 336 healthy adults who received tecovirimat capsules twice a day for 14 days. Tecovirimat for injection was also tested in 26 healthy adults. No serious problems occurred in any of the participants in these studies. During the 2022 monkeypox outbreak in the US, tecovirimat capsules have also been given to more than 230 people with poxvirus infection, including patients with monkeypox, as of July 2022; side effects are being monitored but no serious problems with tecovirimat have been reported so far. Still, tecovirimat may cause some adverse events. There also may be other adverse events that we cannot predict. The most common adverse events in people who have taken tecovirimat were:

- Headache
- Nausea
- Vomiting
- Stomach pain
- Dizziness (only with IV tecovirimat)
- Pain/swelling/redness at the injection site (only with IV tecovirimat)

Low blood sugar can occur when tecovirimat is taken with repaglinide, a medicine used to treat type 2 diabetes. If you are taking repaglinide, tell your healthcare provider if you get any of these symptoms of low blood sugar:

- Headache
- Hunger
- Dizziness
- Sweating
- Fast heartbeat
- Drowsiness
- Feeling jittery or shaky
- Confusion
- Weakness
- Irritability

As with any medication, there is a potential risk of an allergic reaction. An allergic reaction after receiving tecovirimat could include a rash, difficulty breathing, wheezing, sudden drop in blood pressure causing dizziness or fainting, swelling (around the mouth, throat, or eyes), fast pulse, and sweating.

During tecovirimat treatment, a small amount of your blood (5 mL or 1 teaspoon) may be taken for tests. Possible risks of taking blood are brief pain, bleeding, bruising of the skin where the needle enters, soreness and swelling at that spot, and possible infection at that spot. A trained person skilled in blood collection will collect your blood sample using a sterile technique. Please tell the doctor about any medical conditions or problems that you have.

ARE THERE RISKS RELATED TO PREGNANCY OR NURSING?

Tecovirimat has not been studied in pregnant or nursing people. It is not known if giving tecovirimat to a pregnant person would hurt the unborn child. Tecovirimat has been tested on pregnant mice and rabbits. There were no serious problems in the unborn animals. Poxviruses during pregnancy can cause serious harm to the pregnant person and unborn baby. Given that your illness is serious, the potential benefits of tecovirimat likely outweigh the risks. In animal studies, tecovirimat was present in animal milk. When a drug is present in animal milk it is likely to be present in human milk. Because of the potential for virus transmission through direct contact with the breastfed infant, breastfeeding is not recommended while the nursing individual has active lesions. A lactating person should consider pausing breastfeeding and consider pumping and discarding breast milk during treatment.

WHAT OTHER CHOICES DO I HAVE?

There are two vaccines (Jynneos and ACAM2000), approved by the FDA, for prevention of smallpox and monkeypox disease. The vaccines can help protect people against smallpox, monkeypox or some other poxvirus infections when given ***before*** exposure to the virus. It may also help even ***after*** exposure to virus if the vaccine is given soon after exposure (within 4 days) or may lessen the symptoms of disease when given between 4-14 days after exposure. But how well the vaccine may protect ***after*** exposure and whether the way a person was exposed affects how protective the vaccine is not known. The vaccines will not treat or get rid of the poxvirus infection or disease, if you have them. There is no proven way to treat poxviruses, but research is ongoing. You may benefit from supportive therapy (such as IV fluids, or medicine to control fever or pain) and antibiotics for any bacterial infections you may have. There may be other medications that your doctor may consider using to treat your infection. There may also be research studies looking at other new treatments for poxviruses. You should discuss any questions you have and other choices you may have with your doctor.

WHAT ARE MY COSTS?

CDC is providing tecovirimat for free. Other costs of the hospital and medical care will not be paid by CDC. Other costs will need to be paid by your insurer, Medicare, Medicaid, or you.

WHAT IF YOU REFUSE TECOVIRIMAT TREATMENT?

You have the right to refuse tecovirimat. Talk to the doctor if you do not want to get tecovirimat. Your will explain how it may affect your health and will tell you about other treatments. You also have the right to stop tecovirimat at any time without penalty especially if you have any side effects that you cannot tolerate. It will not change your regular medical care if you decide not to take it.

WHAT HAPPENS IF YOU ARE HARMED?
You will get immediate medical care if you are harmed from getting tecovirimat treatment. But CDC will not give this care. CDC does not normally pay for harm done to you because of being in a program like this. Thus, you or your insurer (such as Medicare or Medicaid) will have to pay for any care that is needed. But, you are not giving up any of your rights by signing this consent form and agreeing to be treated with tecovirimat in this program.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that provides compensation to certain people as a result of serious injury or death from certain medicines or vaccines, including this medicine. You can learn more about this program by visiting www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT ABOUT PRIVACY?
We will keep all facts about you private to the extent allowed by applicable law. People who work for CDC, FDA, U.S. Department of Health and Human Services, and local/state health authorities may look at your tecovirimat treatment and related medical records to ensure and monitor the appropriate and safe use of tecovirimat. If this information is shared with anyone else such as your name and personal information will not be used or listed. If we share photos, we will only use those that will not reveal your identity. This includes reports or any publications such as articles in scientific journals. But, CDC is allowed to give your name to public health or medical people who, for example, need to find out how you got the infection and how to prevent other cases.

WHAT IF I HAVE PROBLEMS OR QUESTIONS?
If you have questions about this treatment program or feel that you or your child have been harmed as a result of participation in this program, please contact your treating physician [contact info:_____]. If you have questions about your rights as a participant in this program, please call CDC's Human Research Protection Office at 1 (800) 584-8814 and say that you are calling about CDC protocol #6402. Leave a brief message with your name and phone number. Someone will call you back as soon as possible.

WRITTEN INFORMED CONSENT FOR TREATMENT WITH TECOVIRIMAT
I have read the form or it has been read to me. I have been given a chance to ask questions and my questions have been answered. I agree to get (or have my child get) tecovirimat.

I also agree that any samples I/my child give can be stored for future orthopoxvirus-related testing:
☐s ☐

Print Patient's Name:_____

Patient's/Parent's Signature: _____ Date:_____

Note: If patient or parent/guardian is unable to sign, a next of kin may sign.
Legally Authorized Representative Signature: _____
Print Name: _____
Date: _____

TRANSLATOR DOCUMENTATION (if applicable)
Translator to document if patient gave informed consent through another language other than English:
I have translated this form into the _____ language.
Print Name: _____
Translator's Signature:_____ Date: _____

A copy of the signed informed consent should be maintained at the treating facility/institution. It does NOT need to return to CDC unless the treating facility/institution cannot maintain copies.

IF OBTAINING INFORMED CONSENT IS NOT FEASIBLE

In the event that obtaining informed consent is not feasible because the patient is unable to respond and make wishes known about tecovirimat treatment *and* no legal guardian or next-of-kin is present the following provides for the treating physician to make a clinical determination to treat with tecovirimat provided that the treating physician and an independent physician certifies to the following within 3 working days of initiating treatment with tecovirimat:

1. Patient is confronted by a life-threatening situation necessitating the use of tecovirimat.
2. Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally-effective consent from, the patient.
3. Time is not sufficient to obtain consent from the patient's legal representative.
4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

☐ Document as such in the patient's medical record and ensure the patient or patient's legally authorized representative is made aware that tecovirimat was administered for uses for which it is not FDA-approved.

☐ Name & signature of treating physician who made the determination to administer tecovirimat to patient when informed consent could not be obtained:

_____	_____	_____
Name	Signature	Date

☐ Name & signature of second physician, who is not otherwise participating in this treatment protocol, reviewing and evaluating decision to administer tecovirimat to patient:

_____	_____	_____
Name	Signature	Date

Notify CDC via email (regaffairs@cdc.gov) within 3 working days of tecovirimat initiation when the treatment determination was made based on the above-mentioned certification by the treating physician and an independent physician.