FORM A: Patient Intake Form

To Be Completed by Treating Physician for Inpatients and Outpatients Prior to First Dose of Tecovirimat (≤ 24 hours) (Page 1 of 6)

Date (MM/DD/YY): _____/_____/_____

HOSPITAL INFORMATION

Treating Physician Name: _____

Telephone Number: _____ **Fax number:** _____

Email address: _____

Hospital/Medical Facility Name and Address:

_____

_____

_____

DEMOGRAPHICS

Patient Name: _____

Hospital-assigned Patient ID: _____

Date of Birth (MM/DD/YY): _____ **Age:** _____**years** _____**months**

Sex: ☐ Male ☐ Female

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Race:

☐ African American/Black
☐ American Indian or Alaska Native
☐ Asian
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Other

ELIGIBILITY CRITERIA for TECOVIRIMAT TREATMENT

1. Primary Treatment for Orthopoxvirus Infections

1. Does the patient have an orthopoxvirus infection that has been confirmed by laboratory diagnostic testing or is suspected based on known exposure(s) and/or clinical manifestations of disease, while laboratory confirmation may be pending?
   ☐ Yes ☐ No
   Indicate orthopoxvirus species:_____

OR

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2. Secondary Treatment for Complications Resulting from Vaccinia Vaccination/Exposure

2a. Has the patient developed vaccine-related complications from being vaccinated with vaccinia vaccine?
☐ Yes ☐ No If Yes, Date of Vaccination: _____

OR

2b. Has the patient been exposed to vaccinia virus without vaccination and developed vaccinia-related complications? ☐ Yes ☐ No Date of Exposure: _____

- What is the complication? (check one below)
  - ☐ Severe generalized vaccinia (GV)
    Describe the extent of lesions and other systemic manifestations of GV:
    _____
    _____
  - ☐ Eczema vaccinatum
  - ☐ Progressive vaccinia (vaccinia necrosum)
  - ☐ Serious inadvertent inoculation: describe how assessed and systemic findings
    _____
    _____

3. Eligibility for IV Tecovirimat

1. Is patient unable to take oral therapy or is there a concern that oral drug absorption may be altered (e.g., by gastrointestinal disfunction)?
   ☐ Yes ☐ No
   If yes, provide details on patient's condition: _____
   _____
   _____

INELIGIBILITY/STOPPING CRITERIA for TECOVIRIMAT TREATMENT

(if any of the following is Yes, tecovirimat treatment cannot be initiated or continue)

1. Unwilling to sign informed consent.
   ☐ Yes ☐ No
2. Refuse tecovirimat treatment.
   ☐ Yes ☐ No
3. Known allergy to tecovirimat and/or excipients of tecovirimat?
   ☐ Yes ☐ No
4. Negative laboratory results for orthopoxvirus in individuals whose tecovirimat treatment is initiated based on clinical manifestations of disease prior to laboratory results.
   ☐ Yes ☐ No
5. For IV tecovirimat only: patients with severe renal impairment (creatinine clearance <30 mL/min)
   ☐ Yes ☐ No

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MEDICAL HISTORY

Date of illness onset (MM/DD/YY): _____/_____/_____
Date and time of exposure (if known) (MM/DD/YY): _____/_____/_____ _____Time (24h)
Date and time of smallpox vaccination (if known) (MM/DD/YY): ____/____/_____ _____Time (24h)
☐ ACAM2000 ☐ MVA
If vaccinated with ACAM2000, was there a documented vaccine "take?"
☐ Yes ☐ No If Yes, Date:_____

Pre-existing conditions:

1. Immunocompromising condition (i.e.: HIV/AIDS, atopic dermatitis or other skin disease, congenital/acquired immune defects, autoimmune/connective tissue disorders, bone marrow/organ transplants, leukemia/lymphoma/other cancers)?
   ☐ Yes ☐ No Type of condition: _____

2. Treatment with a medication affecting immunocompetency?
   ☐ Yes ☐ No Medication name(s): _____

3. History of superinfection? ☐ Yes ☐ No
   (If yes, describe) _____

4. Other pre-existing conditions? ☐ Yes ☐ No
   If yes, list: _____

Therapeutic Intervention: List all medications such as VIGIV and/or other antivirals administered for the treatment of orthopoxvirus infection (*tecovirimat can be used in conjunction with VIGIV or other therapies based on treating physician's clinical judgment)*:

Medication	Date of administration	Dose	Route of administration	Outcome

Other Concomitant Medications:

Note: Co-administration with repaglinide may cause hypoglycemia. Monitor blood glucose and monitor for hypoglycemic symptoms during co-administration.

Medication:	Dosage/route of administration:
Medication:	Dosage/route of administration:
Medication:	Dosage/route of administration:
Medication:	Dosage/route of administration:
Medication:	Dosage/route of administration:

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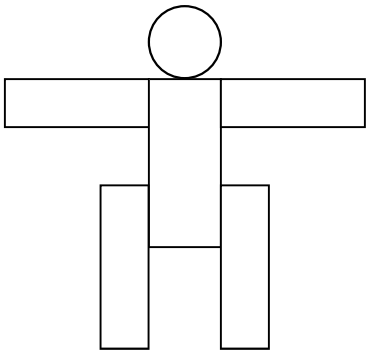
SIGNS/SYMPTOMS ON INITIAL PRESENTATION

Program & Baseline Physical Assessment:
Date and Time of Assessment: _____ (MM/DD/YY) _____ Time (24h)

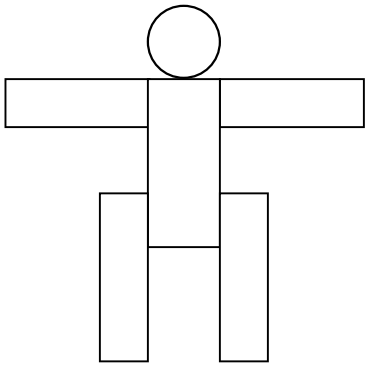
Presenting Signs/Symptoms:
Number of Lesions: ☐ < 10 lesions ☐ 10–100 lesions ☐ > 100 lesions
Size of Maximal Lesion: _____ mm
Percent of body affected: _____ %

Distribution of Lesions:

Ventral



Dorsal



LESION PHOTOS

Were lesion photos taken? ☐ Yes (Date taken: _____) If yes, send photos to CDC.
☐ No

VITAL SIGNS

Height: _____
Weight (kg): _____
Pulse (bpm): _____
Blood Pressure (sitting)
Systolic (mmHg): _____
Diastolic (mmHg): _____
Respiratory Rate (rpm): _____
Temperature (ºF): _____

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Baseline Physical Assessment	
Body System	**Comment (if abnormal)**
General ☐ Normal ☐ Abnormal	
HEENT and Neck ☐ Normal ☐ Abnormal	
Lungs ☐ Normal ☐ Abnormal	
Cardiac ☐ Normal ☐ Abnormal	
Abdomen ☐ Normal ☐ Abnormal	
Extremities ☐ Normal ☐ Abnormal	
Neurological ☐ Normal ☐ Abnormal	
Other ☐ Normal ☐ Abnormal	

Clinical Narrative (please include site and circumstances of exposure and medical condition at time of program enrollment; may attach clinical narrative from medical chart):

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CLINICAL LABORATORY RESULTS (may attach laboratory printouts or reports)

Laboratory Parameters		Date/time of sample	Value (indicate units)
HEMATOLOGY	Prothrombin time		
	Partial thromboplastin time		
	Platelet count		
	Hemoglobin		
	Hematocrit		
	RBC count		
	Absolute WBC		
	Differential count		
CHEMISTRY	Calcium		
	Magnesium		
	Sodium		
	Potassium		
	Chloride		
	Bicarbonate		
	Phosphorous		
	Urea		
	Creatinine		
	Calculated creatinine clearance		
	Glucose		
	Uric acid		
	Albumin		
	Total bilirubin		
	Total protein		
	Aspartate transaminase		
	Alanine transaminase		
	Alkaline phosphatase		
URINALYSIS	Human Chorionic Gonadotropin (hCG)		
	Protein		
	Hemoglobin		
	Glucose		
	Microscopic analysis		

SERUM IMMUNOCHEMISTRY AND SCAB/LESION* SAMPLING

Were samples collected & sent to CDC for immunochemistry, PCR, viral culture, and resistance testing? ☐ Yes ☐ No

Sample type	Date of sample collection	Date sample sent to CDC

*Lesion sampling will be based on the patient's clinical presentation and progression (e.g. based on evaluation of photos).

TECOVIRIMAT TREATMENT INITIATION

Was tecovirimat given to this patient? ☐ Yes ☐ No Route of Administration (at initiation) ☐ Oral ☐ IV

What dose was prescribed for this patient? _____ mg _____ times per day

What is the planned duration of treatment? _____days

On what date /time was the first dose? ____/_____/_____ (*MM/DD/YYYY*) _____:_____ (*hh:mm am/pm*)

Patient Name: _____ **Hospital-assigned Patient ID:** _____