Tecovirimat Clinical Outcome Form

Treating clinician or designee should complete this form during and after completion of the tecovirimat treatment course and return to CDC with 3 working days of last patient follow-up via email regaffairs@cdc.gov or upload to secure ShareFile at https://centersfordiseasecontrol.sharefile.com/r-r3941801ebcbd4002b4dfe98e314ec697.

PATIENT INFORMATION

Patient Name (first and last name):

HOSPITAL INFORMATION

Hospital/Medical Facility Name

Name of individual completing this form	**Contact information (email address, telephone number)**

TECOVIRIMAT TREATMENT INFORMATION

Route	**Date of 1st dose**	**Dose (mg)**	**Dose frequency**	**Duration of therapy (days)**
Oral				
IV				

- Did patient report taking oral tecovirimat with a meal containing about 600 calories and 25 grams of fat?
  ☐ Yes ☐ No ☐ N/A ☐ Unknown
- Was oral tecovirimat given via nasogastric (NG) tube?
  ☐ Yes ☐ No ☐ N/A ☐ Unknown

Any serious adverse events* with tecovirimat treatment? ☐ Yes ☐ No ☐ Unknown

- If yes, describe the SAE:
- Was the SAE reported to FDA MedWatch? ☐ Yes ☐ No ☐ Unknown
- If No or Unknown, please email a completed PDF MedWatch Form to regaffairs@cdc.gov.

**SAE defined as death, life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; congenital anomaly/birth defect; an important medical event that based on appropriate medical judgement may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed.*

CLINICAL OUTCOME

Was patient hospitalized after tecovirimat initiation? ☐ Yes ☐ No ☐ Unknown

- Reason for admission:_____
- Hospital duration (# days): _____

Admitted to ICU? ☐ Yes ☐ No ☐ Unknown

- Duration of intensive care (# days):_____

Time to first observed (including patient-reported) improvement

- Signs/symptoms first started to improve on tecovirimat treatment day # _____
- Describe the improvements:

What was the outcome of the patient?

☐ Recovered from orthopoxvirus infection without sequelae
☐ Recovered from orthopoxvirus infection with sequelae
Describe sequelae: _____
☐ Not recovered from orthopoxvirus infection (e.g., persistence of residual lesions)
Describe: _____
☐ Death If patient died, when did patient die (date)? _____
What was the cause of death? _____

ASSESSMENT OF LESIONS DURING AND AFTER TECOVIRIMAT TREATMENT

Conduct patient follow-up once during treatment **(A or B)** and 7-10 days post treatment **(C)**. Day on which post-treatment follow-up is conducted is flexible (indicate date of assessment and findings on that day). Patient follow-ups may be conducted via **telemedicine.**

	During Tecovirimat Treatment		**After Completion of Tecovirimat Course**	
	Day 1-7 (A)	**Day 8-14 (B)**	**7-10 days after last tecovirimat dose (C)**	**Upon discharge (for inpatients only)**
Date of assessment				
Tecovirimat treatment day # *or* # days after last tecovirimat dose				
Approximate # of lesions				
% of body affected				
Size of maximal lesion (mm)				
Any new lesions? *If yes, send new lesion samples to CDC for resistance testing,* ***if feasible***	☐ Yes ☐ No Date of new lesions:	☐ Yes ☐ No Date of new lesions:	☐ Yes ☐ No Date of new lesions:	☐ Yes ☐ No Date of new lesions:
All lesions crusted and healed with new layer of skin?	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:
Evidence of scarring or depigmentation?	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:
Strictures in the genital region?	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:	☐ Yes ☐ No Describe:

Describe the anatomical locations of the lesions and how the lesions changed throughout the treatment course (e.g., size, location, rate of healing). *If any photos of lesions were taken, please include with the dates the photos were taken.*
<u>OPTIONAL</u> CLINICAL LABORATORY TESTING Attach a copy of clinical laboratory results (e.g., hematology, chemistry, urinalysis) if any were performed per treating physician's clinical judgment depending on the patient's underlying clinical conditions to monitor the safety of tecovirimat treatment as appropriate (e.g., baseline, during, post treatment).

OPTIONAL: LESION/SCAB* SAMPLING FOR RESISTANCE TESTING AT CDC **Complete this section only if any samples were collected and shipped to CDC**			
Were samples collected & sent to CDC? ☐ Yes ☐ No			
Sample type	**Anatomical location of lesion**	**Date of sample collection**	**Date sample sent to CDC**

* Samples of any new lesions that developed during tecovirimat treatment and after treatment completion to CDC for resistance testing.

OPTIONAL: PLASMA PHARMACOKINETIC (PK) SAMPLING **Complete this section only if any samples were collected and shipped to Alturas**		
Date and Time of PK Sample Collection	**Date and Time of Tecovirimat Dose**	**Tecovirimat Dose (oral, NG tube, or IV) on PK collection** **Dose taken with meal?**
____/_____/_____ ____:____	____/_____/_____ ____:____	☐ Oral ☐ NG Tube ☐ IV
____/_____/_____ ____:____	____/_____/_____ ____:____	☐ Oral ☐ NG Tube ☐ IV