Optional Clinical Outcome Form

If feasible, conduct patient follow-up within **3-14 calendar days** after completion of treatment. Please return this form to CDC within **7 calendar days** of last patient follow-up, if conducted, via email regaffairs@cdc.gov or upload to secure ShareFile at https://centersfordiseasecontrol.sharefile.com/r-r3941801ebcbd4002b4dfe98e314ec697.

Patient Name (first and last name):	**Hospital/Medical Facility-assigned Patient ID:**
Hospital/Medical Facility Name	**Hospital/Medical Facility Address**
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				☐ Check if by NG tube
IV				

If therapy duration was not for 14 days, indicate reason(s):

- ☐ Discontinued due to adverse events
- ☐ Shorter therapy (<14 days) due to symptom resolution
- ☐ Longer therapy (>14 days) due to continuing symptoms
- ☐ Other, specify:

ASSESSMENT OF LESIONS DURING AND AFTER TECOVIRIMAT TREATMENT

Time to first observed (including patient-reported) improvement

- Lesions or pain first started to improve on tecovirimat treatment day # _____
- Lesions and pain fully resolved† on tecovirimat treatment day # _____

†*Scabs fall off on their own and new healthy skin formed underneath*

Conduct patient follow-up within 3-14 days after completion of tecovirimat. Follow-up may be conducted via **telemedicine.**

Date of patient follow-up: _____

Did new lesions develop after starting tecovirimat?	☐ Yes ☐ No ☐ Unk
If yes:	
Did new lesions develop 2–5 days after starting tecovirimat?	☐ Yes ☐ No ☐ Unk
Did new lesions develop 6–10 days after starting tecovirimat?	☐ Yes ☐ No ☐ Unk
Did new lesions develop 11–14 days after starting tecovirimat?	☐ Yes ☐ No ☐ Unk
Are lesions still present after completion of tecovirimat treatment?	☐ Yes ☐ No ☐ Unk
If yes:	
Approximate # of lesions that persist after treatment	_____
% of body still has lesions	_____
Size of maximal lesion that persist after treatment (mm)	_____
Evidence of scarring or depigmentation?	☐ Yes ☐ No ☐ Unk ☐ N/A
Strictures in the urogenital region?	☐ Yes ☐ No ☐ Unk ☐ N/A

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.*

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):_____

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? _____

Any life-threatening or serious adverse events* with tecovirimat treatment? ☐ Yes ☐ No ☐ Unknown

- If yes, describe:

- Was the MedWatch form completed and submitted to CDC (regaffairs@cdc.gov)? ☐ 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 aforementioned outcomes.*

OPTIONAL 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 ☐ Unknown

Sample type	Anatomical location of lesion	Date of sample collection	Date sample sent to CDC

* Samples of any new lesions that develop 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 Analytics

Were samples collected & sent to CDC? ☐ Yes ☐ No ☐ Unknown

Date and Time of PK Sample Collection	Date and Time of Tecovirimat Dose	Tecovirimat dosing at time of PK collection		
		Route	Dosage (mg)	Frequency
____/_____/_____ ____:____	____/_____/_____ ____:____	☐ Oral ☐ NG Tube ☐ IV		
____/_____/_____ ____:____	____/_____/_____ ____:____	☐ Oral ☐ NG Tube ☐ IV		

Patient Name (First and Last)* **Hospital/Facility-assigned patient ID**