Acute Flaccid Myelitis (AFM) Case Determination Standard Operating Procedure

I.	**Background**	AFM is a type of acute flaccid paralysis characterized by an acute or sub-acute onset of flaccid limb weakness, sometimes accompanied by cranial nerve dysfunction (such as facial drooping or difficulty speaking). In most cases, distinctive lesions primarily in the gray matter of the spinal cord are seen on neuroimaging. CDC has been actively investigating suspected AFM cases, testing specimens, and reviewing neurologic findings in order to monitor the incidence of AFM since August 2014, when there was an apparent increase in patients with this illness. Through the establishment of standardized surveillance for AFM, CDC is working closely with health departments and health professionals to increase awareness, information sharing, and lab testing to better understand the occurrence, risk factors, and possible causes of AFM.
II.	**Purpose**	This document outlines the procedures for classifying a patient under investigation (PUI) of AFM. All PUIs of AFM are investigated to determine whether they should be classified as confirmed, probable, suspect, or not a case.
III.	**2022 CSTE Case definition**	**Clinical Criteria** An illness with onset of acute flaccid* weakness of one or more limbs, AND Absence of a clear alternative diagnosis attributable to a nationally notifiable condition **Laboratory Criteria** *Confirmatory laboratory evidence:* • A magnetic resonance image (MRI) showing spinal cord lesion with predominant gray matter involvement† and spanning one or more vertebral segments, **AND** • Excluding persons with gray matter lesions in the spinal cord resulting from physician diagnosed malignancy, vascular disease, or anatomic abnormalities *Presumptive laboratory evidence:* • MRI showing spinal cord lesion where gray matter involvement† is present but predominance cannot be determined, **AND** • Excluding persons with gray matter lesions in the spinal cord resulting from physician diagnosed malignancy, vascular disease, or anatomic abnormalities *Supportive laboratory evidence:* • MRI showing a spinal cord lesion in at least some gray matter† and spanning one or more vertebral segments, **AND** • Excluding persons with gray matter lesions in the spinal cord resulting from physician diagnosed malignancy, vascular disease, or anatomic abnormalities **Case Classification** **<u>Confirmed:</u>** • Meets clinical criteria with confirmatory laboratory/imaging evidence, **OR** • Meets other classification criteria **<u>Probable:</u>** • Meets clinical criteria with presumptive laboratory/imaging evidence

		<u>Suspect:</u> • Meets clinical criteria with supportive laboratory/imaging evidence, **AND** • Available information is insufficient to classify case as probable or confirmed **<u>Other Classification Criteria</u>** • Autopsy findings that include histopathologic evidence of inflammation largely involving the anterior horn of the spinal cord spanning one or more vertebral segments, **AND** • Excluding persons with gray matter lesions in the spinal cord resulting from physician diagnosed malignancy, vascular disease, or anatomic abnormalities, **AND** • Absence of a clear alternative diagnosis attributable to a nationally notifiable condition ** Low muscle tone, limp, hanging loosely, not spastic or contracted* *† Terms in the spinal cord MRI report such as "affecting gray matter," "affecting the anterior horn or anterior horn cells," "affecting the central cord," "anterior myelitis," or "poliomyelitis" would all be consistent with this terminology.* **Comment** To provide consistency in case classification, review of case information and assignment of final case classification for all suspected AFM cases will be done by experts in national AFM surveillance. This is similar to the review required for final classification of paralytic polio cases.

IV.	**Procedures**	
	a. Hospital	1. Clinician suspects AFM in a patient with acute onset of flaccid weakness. Any person that meets the clinical criteria for AFM should be considered a suspected AFM case and information sent to CDC through the health department. 2. Clinician contacts local or state health department 3. Clinician fills out CDC AFM patient summary form (PSF) with public health 4. Clinician collects appropriate samples (CSF, blood, serum, stool, respiratory) https://www.cdc.gov/acute-flaccid-myelitis/hcp/specimen-collection.html 5. Upon request from public health, clinician will provide complete medical record information for all Confirmed and Probable cases at 60 days from onset of limb weakness.

	b. Public Health	1. Discusses case with clinician and ensures patient meets clinical criteria 2. Alerts CDC of suspected case of AFM 3. Obtains and coordinates secure submission of MRI report, images and neurology consult from clinician (see annex for secure online upload of MRI images) 4. Coordinates shipping samples to CDC AFM Laboratory 5. Conducts a 60-day follow-up with confirmed and probable cases 6. At the same time of the 60-day follow-up, obtains and coordinates secure submission of clinical notes (admission history and physical, neurology and infectious disease consult notes, and discharge summary) 7. Patients will be classified by national AFM experts according to the CSTE definition. After review, patient classification is relayed to the clinician.
	c. CDC	1. CDC AFM team reviews new suspect cases to ensure reporting criteria is met 2. PSFs, neurology consults, MRI images and reports are then sent to neurology experts in AFM, supported by CDC and composed of neurologists specializing in spinal cord diseases from academic centers and CDC, for evaluation and to provide an official surveillance classification 3. At 60 days from initial onset of limb weakness, CDC will request more information from the health department for all confirmed and probable cases. CDC will request clinical notes (admission history and physical, neurology and infectious disease consult notes, and discharge summary) 4. Complete medical records will be collected for neurology panel to abstract from and further analyze cases. Information collected from complete medical records will be used for further sub-classification of cases. Sub-classification will divide the confirmed cases into more specific diagnoses, such as transverse myelitis, anti-MOG antibody disease, among other spinal vascular conditions

V.	**Annex**	• Link to CSTE AFM Position Statement 17-ID-01: https://ndc.services.cdc.gov/case-definitions/acute-flaccid-myelitis-2022/ • Patient Summary Form: https://www.cdc.gov/acute-flaccid-myelitis/downloads/patient-summary-form.pdf • Specimen collection guide: https://www.cdc.gov/acute-flaccid-myelitis/hcp/specimen-collection.html • Laboratory specimen submission: https://www.cdc.gov/laboratory/specimen-submission/form.html

		• Physician Consult and Support Portal: https://wearesrna.org/living-with-myelitis/resources/afm-physician-support-portal/
		
		• MRI image upload using secure FileZilla website:
		  ○ https://filezilla-project.org/ (select "Download FileZilla Client")
		  ○ Once downloaded, open FileZilla:
		  ○ Go to File > Site Manager > New Site, enter in 'cdc dvd_eb ftp'
		  ○ In host window enter: eftp.cdc.gov
		  ○ In Port enter: 22
		  ○ For Protocol select: SFTP - SSH File Transfer Protocol
		  ○ Logon Type: Normal
		  ○ User: DVD_EB_SXFTP_XX ("XX" is the 2 letter abbreviation for the state needing access)
		  ○ Password: Enter password provided by phone
		
		• AMBRA link for MRI image upload via secure cloud: https://afmstudies.ambrahealth.com/share/afm_outside_uploads