DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

MEMORANDUM

DATE: September 26, 2022

TO: Principal Investigators, Clinical Research Associates, and Operations/Statistics Offices of NCI CTEP-Supported Clinical Trials Networks & Consortia and DCP-Supported NCI Community Oncology Research Program (NCORP) Research Bases

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SUBJECT: Guidance for Administration of the Jynneos Monkeypox Vaccine and Tecovirimat to Study Participants on CTEP IND Studies

The purpose of this memorandum is to provide guidance to the Cancer Therapy Evaluation Program (CTEP) and NCI Community Oncology Research Program (NCORP) clinical research communities for the administration of the Jynneos Monkeypox Vaccine and Tecovirimat for participants in studies being conducted under an IND held by the Cancer Therapy Evaluation Program (CTEP), DCTD, NCI. No formal protocol amendments will be required for use of the Jynneos Monkeypox Vaccine as described below for CTEP IND studies.

GENERAL GUIDANCE:

- Although the Jynneos Monkeypox Vaccine may be considered a live virus vaccine, it is not considered a live virus vaccine in terms of eligibility or administration in CTEP IND clinical trials. The use of the term 'live virus' vaccine has been used in CTEP protocols interchangeably with 'replication competent' vaccine. Even though the Jynneos Monkeypox Vaccine can be considered a live virus because it does infect cells upon injection, it is 'replication incompetent,' so the localized infection caused by the vaccine cannot spread, and therefore poses a very low risk of complications associated with viremia. Therefore, eligibility criteria in CTEP IND trials excluding participants who have received a live virus vaccine do **not** apply to those participants who have received the Jynneos Monkeypox Vaccine and administration of this vaccine during the conduct of a CTEP IND trial would not result in a protocol deviation for that reason.

- Use of the Jynneos Monkeypox Vaccine is per investigator discretion. However, CTEP does recommend that all study participants who are determined to be at high risk for monkeypox infection maintain a high level of awareness and be vaccinated, unless otherwise contraindicated.

- CTEP understands that the scheduling for administration of the Jynneos Monkeypox Vaccine might not be flexible, but whenever possible the following guidelines are recommended:

    - In participants who have not yet started treatment, the vaccine should be administered at least 3 days prior to start of treatment when possible.

    - In participants who are receiving study infusion therapy, the vaccine should not be administered on an infusion day. Where possible, the vaccine should be administered during an off week, or at least a week apart from an infusion day. A minimum gap of at least 3 days is strongly recommended, based on CDC guidance that most vaccine-related adverse events (AEs) occur within 3 days of injection.

    - In patients who are receiving daily oral therapy, the vaccine should not be administered within a week of any dose modification.

    - In patients with an arm that has undergone lymphadenectomy, the vaccine should be administered in the opposite arm.

    - Administration of the vaccine should be documented as a concomitant medication, except in trials for which concomitant medications are not collected.

- Regarding the use of the antiviral drug tecovirimat (TPOXX), please see the CDC reference below on "Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox." Physicians should review and consider the concomitant medications that their study participants are taking before prescribing tecovirimat.

Additional Informational Resources from the FDA and CDC are provided below:

FDA Monkeypox Response | FDA

CDC Monkeypox Information for Healthcare Professionals | CDC

CDC Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | CDC

CDC Patient's Guide to Monkeypox Treatment with TPOXX | Monkeypox | Poxvirus | CDC