Steve Sisolak
Governor

Richard Whitley, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
Helping people. It's who we are and what we do.

Lisa Sherych
Administrator

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

Technical Bulletin

Date: **September 19, 2022**
Topic: **JYNNEOS Vaccine Authorized by the FDA for Emergency Use Authorization**
Contact: **Kristy Zigenis, Nevada State Immunization Program**
To: **All Health Care Providers and Facilities; Pharmacists; Pharmacy Technicians; Local Health Authorities**

Background:
In 2019, the JYNNEOS vaccine was approved by the U.S. Food and Drug Administration (FDA) for the prevention of smallpox and monkeypox disease in individuals aged 18 years and older. At the time of approval, the JYNNEOS vaccine was recommended as a two-dose, subcutaneous injection of 0.5 mL spaced 28 days apart. Due to emerging public health needs and limited national supply of JYNNEOS vaccines currently available, the FDA has been working diligently with other government partners to accelerate the submission of information needed to make additional U.S. doses of JYNNEOS available.

On August 9, 2022, the FDA determined that the JYNNEOS vaccine met the criteria needed for Emergency Use Authorization (EUA). As the only vaccine that is approved for the prevention of monkeypox in the United States, this EUA will increase the total number of doses available for use in the United States up to five-fold.

This technical bulletin summarizes the recent JYNNEOS vaccine EUA and recommendations currently established by the FDA and the Centers for Disease Control and Prevention (CDC).

Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine
This EUA allows health care providers to administer the JYNNEOS vaccine to individuals determined to be at high risk for monkeypox infection according to the tables below.

Standard regimen — each dose to be administered by subcutaneous injection into the fatty tissue over the triceps area in the upper arm

Recipient age	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
<18 years of age and those >18 where intradermal injection is contraindicated	0.5 mL	2	28 days

Alternative regimen — each dose to be administered by intradermal injection (ID) into the volar surface of the forearm

Recipient age	Injection volume	Recommended number of doses	Recommended internal between 1st and 2nd dose
>18 years of age	0.1 mL	2	28 days

**According to the Centers for Disease Control and Prevention, individuals who receive a JYNNEOS vaccine are not considered vaccinated until 2 weeks after they receive the second dose of the vaccine. All JYNNEOS vaccines should be administered by subcutaneous injection to individuals of any age who are determined to be at high risk for monkeypox infection and have a history of developing keloid scars.

It is important to note the storage and handling requirements and routes of administration for the JYNNEOS vaccine. The JYNNEOS vaccine ***does not*** use diluent. Allow the vaccine to thaw and reach room temperature before use. Once thawed, the vaccine may be stored in a refrigerator between 2 degrees to 8 degrees Celsius (36 degrees to 46 degrees Fahrenheit) for up to 12 hours. Do not refreeze.

After the first needle puncture, hold the vial between 2 degrees to 8 degrees Celsius (36 degrees to 46 degrees Fahrenheit) for up to 8 hours. After thawing, the total time stored at 2 degrees to 8 degrees Celsius (36 degrees to 46 degrees Fahrenheit) should not exceed 12 hours. A tuberculin syringe with a 27-gauge, 1/4" to 1/2" needle with a short bevel should be used for intradermal vaccine administration. A new sterile needle and syringe should be used for each vaccine drawn and administered.

For more information on administering a JYNNEOS vaccine, the CDC has published quick training videos on "How to administer a JYNNEOS vaccine intradermally" and "Subcutaneous vaccine administration." The CDC has also published a series of images on "Administering JYNNEOS Intradermally" and co-administration of JYNNEOS vaccine with other vaccines on the interim considerations website. If an adverse event is to occur, including but not limited to vaccine administration errors or deviations, a report must be made to the Vaccine Adverse Event Reporting System (VAERS).

The JYNNEOS vaccine information statement has been updated. Below you will find additional information and resources for:

- Any Recipients and/or Caregivers and Healthcare Providers for those individuals determined to be at high risk for monkeypox infection, in addition to a Letter to Healthcare Providers, which includes important prescribing information

Questions:
For updated guidance, review the Division of Public and Behavioral Health Technical Bulletin web page. Email questions to dpbh-avars@health.nv.gov.

Lisa Sherych, Administrator
Division of Public and Behavioral Health

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer