FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT JYNNEOS (SMALLPOX AND MONKEYPOX VACCINE, LIVE, NON-REPLICATING) TO PREVENT MONKEYPOX DISEASE IN INDIVIDUALS DETERMINED TO BE AT HIGH RISK FOR MONKEYPOX INFECTION

You or your child is being offered JYNNEOS to prevent monkeypox disease. This Fact Sheet contains information to help you understand the risks and benefits of receiving JYNNEOS, which you or your child may receive because there is an outbreak of monkeypox.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to:

- Allow use of JYNNEOS given between layers of the skin for prevention of monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection; and
- Allow use of JYNNEOS given beneath the skin for prevention of monkeypox disease to individuals younger than 18 years of age determined to be at high risk for monkeypox infection.

For more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document. JYNNEOS is not approved for use in individuals under 18 years of age in the United States. For individuals 18 years of age and older, JYNNEOS given between layers of skin (intradermally) is not approved in the United States. Read this Fact Sheet for information about JYNNEOS. Talk to your healthcare provider about your options or if you have any questions. Under the EUA, there is an option to accept or refuse JYNNEOS.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS MONKEYPOX?

Monkeypox is a disease caused by infection with the monkeypox virus. Monkeypox virus is part of the same family of viruses as the virus that causes smallpox. Monkeypox symptoms are similar to smallpox symptoms, but milder, and monkeypox is rarely fatal. The monkeypox virus can spread to anyone through close skin-to-skin contact. It can also spread through touching objects, fabrics, and surfaces that have been used by someone with monkeypox or by contact with respiratory secretions. People with monkeypox get a rash that may be located anywhere on the body. The rash will go through several stages, including scabs, before healing. The rash can initially look like pimples or blisters and may be painful or itchy. Other symptoms of monkeypox can include:

- Fever
- Chills
- Swollen lymph nodes
- Exhaustion
- Muscle aches and backache
- Headache
- Respiratory symptoms such as sore throat, nasal congestion, or cough

WHAT IS JYNNEOS?

JYNNEOS is a vaccine FDA-approved for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. In these individuals, JYNNEOS is approved to be given beneath the skin (subcutaneously).

The FDA has authorized the emergency use of JYNNEOS to prevent monkeypox disease in individuals under 18 years of age determined to be at high risk for monkeypox infection. In these individuals, JYNNEOS is authorized to be given beneath the skin (subcutaneously).

There is a limited supply of JYNNEOS. FDA has authorized the emergency use of JYNNEOS given between the layers of the skin (intradermally) to prevent monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection. When given intradermally less vaccine is needed per dose, increasing the vaccine supply.

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD I TELL MY VACCINATION PROVIDER BEFORE I OR MY CHILD TAKES JYNNEOS?

Tell your vaccination provider if you or your child:

- Had an allergic reaction after a previous dose of JYNNEOS or another smallpox vaccine
- Have any allergies
- Have a weakened immune system
- Are pregnant

HOW IS JYNNEOS GIVEN?

For individuals 18 years of age and older, JYNNEOS will be given as an injection between the layers of the skin (intradermally).

For individuals under 18 years of age, JYNNEOS will be given as an injection beneath the skin (subcutaneously).

For all age groups, JYNNEOS is administered as a two-dose series, 4 weeks apart.

WHAT ARE THE INGREDIENTS IN JYNNEOS?

JYNNEOS is a live virus vaccine. JYNNEOS contains Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), a weakened, non-replicating orthopoxvirus. It also contains Tris (tromethamine) and sodium chloride, and may contain small amounts of DNA and protein from the Chicken Embryo Fibroblast cells used to grow the vaccine virus, benzonase, gentamicin, and ciprofloxacin.

HAS JYNNEOS BEEN USED BEFORE?

In clinical trials, approximately 7,800 individuals 18 through 80 years of age received at least one dose of JYNNEOS. Almost all of these individuals received JYNNEOS subcutaneously, which is the FDA-approved way to administer the vaccine.

In a clinical trial, approximately 190 individuals 18 years of age or older received at least one dose of the vaccine given between the layers of the skin (intradermally.

JYNNEOS is not approved for use in individuals under 18 years of age. JYNNEOS has not been studied in individuals under 18 years of age.

WHAT ARE THE RISKS OF JYNNEOS?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported in clinical trials with JYNNEOS include muscle pain, headache, fatigue, nausea, chills, and fever, along with pain, redness, swelling, firmness, and itching at the site of injection.

In some people who received JYNNEOS between the layers of the skin (intradermally), minimal redness or firmess at the injection site lasted for up to several months. Some people who received JYNNEOS between the layers of the skin (intradermally) also reported small, firm lumps or discoloration of the skin at the injection site.

These may not be all the possible side effects of JYNNEOS. Serious and unexpected side effects may occur. The possible side effects of JYNNEOS are being monitored during postmarketing use.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you or your child experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or you/your child's healthcare provider if you/your child have any side effects that bother you/your child or do not go away.

Report vaccine side effects to FDA/CDC **Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "JYNNEOS" in the first line of box #18 of the report form.

In addition, you can report side effects to Bavarian Nordic A/S at 1-844-4BAVARIAN.

WHAT IF I DECIDE NOT TO GET JYNNEOS OR NOT TO HAVE MY CHILD GET JYNNEOS?
Under the EUA, there is an option to accept or refuse JYNNEOS. Should you decide not to receive it or for your child not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING MONKEYPOX?
JYNNEOS is the only vaccine approved or authorized for the prevention of monkeypox in the United States.

CAN I RECEIVE JYNNEOS AT THE SAME TIME AS OTHER VACCINES?
Data have not been submitted to FDA on administration of JYNNEOS at the same time as other vaccines. If you are considering receiving or having your child receive JYNNEOS with other vaccines, discuss your options with your/your child's healthcare provider.

WHAT ABOUT PREGNANCY AND BREASTFEEDING?
If you or your child is pregnant or breastfeeding or if your child is being breastfed, discuss the options with the healthcare provider.

WILL JYNNEOS GIVE ME OR MY CHILD MONKEYPOX?
No. JYNNEOS does not contain the monkeypox virus and cannot give you monkeypox.

ADDITIONAL INFORMATION
If you have questions or to access the most recent JYNNEOS Fact Sheets, please visit https://www.fda.gov/media/160773/download.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

HOW CAN I LEARN MORE?
- Ask the vaccination provider or your healthcare provider
- Visit CDC at https://www.cdc.gov/poxvirus/monkeypox/about.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your local or state public health department.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF JYNNEOS?
At this time, the vaccine provider cannot charge you for the vaccine dose and the vaccine provider must administer the vaccine regardless of your ability to pay administration fees. Vaccine providers may seek appropriate reimbursement from a program or plan that covers Monkeypox vaccine administration fees for the vaccine recipient (vaccine recipient's private insurance company or Medicare/Medicaid reimbursement).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of suspected fraudulent activities related to emergency use of Jynneos are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
An EUA is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current monkeypox outbreak. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of vaccines during the monkeypox outbreak. The unapproved uses of an approved product that are authorized under EUA have not undergone the same type of review by FDA as FDA approved uses.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the unapproved use of the product may be effective to prevent monkeypox during the monkeypox outbreak and that the known and potential benefits of the use outweigh the known and potential risks of the use. All of these criteria must be met to allow for such use of the product during the monkeypox outbreak.

An EUA is in effect for the duration of the monkeypox EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used under emergency use).

Manufactured by: Bavarian Nordic A/S
Hejreskovvej 10a
DK-3490 Kvistgaard
Denmark

August 9, 2022

Galveston County Health District • 409-938-7221 • http://www.gchd.org/
9850 Emmett F Lowry Expy A108, Texas City, TX 77591

Galveston County Health District
Providing credible and responsible public services since 1971

Your Information. Your Rights. Our Responsibilities.

This notice describes how health information about you may be used and disclosed by the Galveston County Health District, and how you can gain access to this information. **Please review it carefully!**

Your Rights:

- Request a copy of your paper or electronic health record.
- Correct your paper or electronic health record.
- Request confidential communication.
- Ask us to limit the information we share.
- Get a copy of this privacy notice.
- Get a list of those with whom we've shared your information.
- Choose someone to act and/or make decisions for you.
- File a complaint if you feel as if your privacy rights have been violated.

Your Choices.

You have some choices in the way that we use and share your health information in regards to:

- Telling family and friends about your condition.
- Providing disaster relief.
- Providing mental health care.
- Marketing our services and raising funds.

Our Uses and Disclosures.

We may use and share your information as we:

- Treat You.
- Run our organization.
- Bill for your services.
- Assist in public health and safety endeavors.
- Participate in or conduct research studies.
- Comply with the law.
- Respond to organ and tissue donation requests.
- Work with a medical examiner or funeral director.
- Address workers' compensation, law enforcement, and other governmental requests.
- Respond to lawsuits and other legal actions.

Your Rights.

When it comes to your health information, you hold certain rights. This section explains and some of the ways in which we can assist you.

- **Retrieve an electronic or paper copy of your health record.** You may ask to see or obtain an electronic or paper copy of your health record and other health information about you that we have on-file. Upon making such a request, we will provide you with a copy of your record or a summary of your health information, usually within thirty (30) days of receiving the request. In doing so, we may charge a reasonable, cost-based fee for labor and material.
- **Request that your health record be corrected.** You may ask us to correct health information about you which you believe to be incorrect or incomplete. If your request is denied, we'll provide you written notification within sixty (60) days of the reason for the denial.
- **Request confidential communications.** You may ask us to contact you in a specific way (i.e. via your home or cell phone), or to mail correspondences to an alternative address. All reasonable requests will be adhered to.
- **Ask that we limit the information about you which we use or share.** You may request that we not use or share certain health information for your treatment or payment. We are not required to agree with this request should we believe that it will adversely affect your care, or if it is impermissible. Should you pay for a service or health care item out-of-pocket in full, may ask that we not share this information for the purpose of payment or operations with your health insurer. Unless precluded by law, we will generally agree to this request.
- **Get a list of those whom we've shared your information with.** You may ask for a list that denotes with whom, why and the frequency that we've shared your health information with over the prior six years. We reply by issuing you with a written notice regarding all permissible disclosures requested. In doing so, we may charge a reasonable, cost-based fee for labor and material.
- **Receive a copy of this privacy notice.** You may ask for a copy of this notice at any time, even if you have agreed to receive the notice electronically. A paper copy will be provided to you promptly.
- **Choose someone to act for or represent you.** If someone is your legal guardian or has medical power of attorney over you, that person can exercise your rights and make choices about your health information. We'll ensure that this person presents proof of this authority prior to observing any of their requests.

- **File a complaint if you feel your rights are violated.** You may complain if you feel we have violated your rights by contacting the Compliance Auditor at 409-938-2213, or via email at rmosquera@gchd.org. Additionally, you may file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by calling 1-877-696-6775, or visiting www.hhs.gov/ocr/privacy/hipaa/complaints/. The Galveston County Health District will not retaliate against you should a complaint be filed.

Your Choices.

For certain health information, you may notify us of your choices about information that we share. If you have a clear preference for how we share your information in the situations described below, please talk to us. Tell us what you want us to do, and we will follow your instructions. In these cases, you have both the right and choice to tell us to:

- Share information with your family, close friends, or others involved in your care.
- Share information in a disaster relief situation.
- *If you are not able to tell us your preference, for example if you are unconscious, we may go ahead and share your information if we believe it is in your best interest. We may also share your information when needed to lessen a serious and imminent threat to health or safety.*
    - In these cases we never share your information unless you give us written permission: marketing purposes, most sharing of psychotherapy notes.

Our Uses and Disclosures.

We typically use or share your health information in the following ways:

- **Treating you**. We can use your health information and share it with other professionals who are treating you (*Example: A doctor treating you for an injury asks another doctor about your overall health condition).*
- **Running our organization**. We can use and share your health information to run our practice, improve your care, and contact you when necessary (*Example: We use health information about you to manage your treatment and services).*
- **Billing for your services**. We can use and share your health information to bill and get payment from health plans or other entities *(Example: We give information about you to your health insurance plan so it will pay for your services).*

We are permitted and at times required to share your information in other ways, usually in ways that contribute to the public good, such as for public health research. In order to share this information however, we must adhere by federal regulation. For more information, please visit: www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html.

- **Help with public health and safety issues.** We can share health information about you for certain situations such as: preventing disease, assisting with product recalls, reporting adverse reactions to medications, reporting suspected abuse, neglect or domestic violence; and/or preventing or reducing a serious threat to anyone's health or safety.
- **Researching**. We can use or share your information for health research when legally permissible.
- **Complying with the law.** We will share information about you if it is required by state or federal law.
- **Responding to organ and tissue donation requests**. We can share health information about you with organ procurement organizations.
- **Working with a medical examiner or funeral director**. We can share health information with a coroner, medical examiner, or funeral director when an individual passes away.
- **Addressing workers' compensation, law enforcement, and other government requests.** We can use or share health information about you for workers' compensation claims, law enforcement purposes or with a law enforcement official, with health oversight agencies for activities authorized by law and for special government functions such as military, national security, and presidential protective services.
- **Responding to lawsuits and legal actions**. We can share health information about you in response to a court or administrative order, or in response to a subpoena.

Our Responsibilities.

- We are required by law to maintain the privacy and security of your protected health information.
- We will let you know promptly if a breach occurs that may have compromised the privacy or security of your personal information.
- All patients must be provided with a copy of this notice upon their initial visit to Galveston County Health District, and we must follow the duties and privacy practices described in this notice.
- We will not use or share your information other than for the purposes described within this notice.

Changes to the Terms of this Notice: We can change the terms of this notice at our discretion, and these changes will apply to all information we have about you. Should this occur, we will mail you a summary of the changes along with a copy of the new notice, which will also be in our office and on our website at www.gchd.org/chn/chnindex.htm.

Effective Date of this Notice: 02/15/2016. Compliance Auditor: Richard Mosquera (p). 409-938-2213 (e). rmosquera@gchd.org

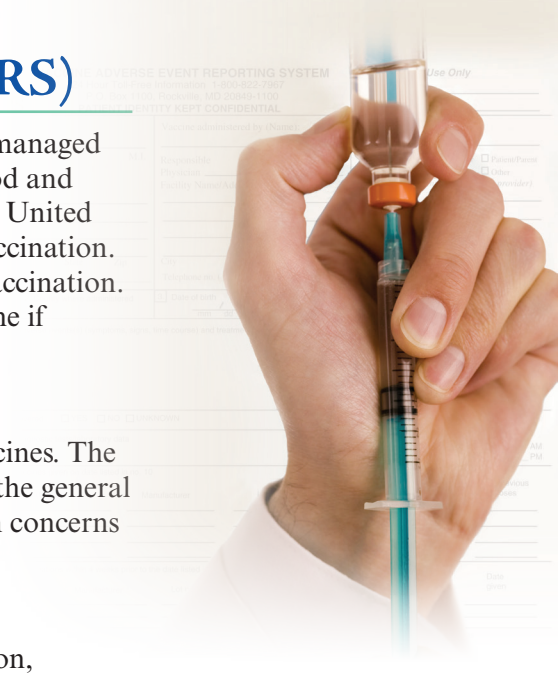
Effective September 1, 2012, the Texas Health records Privacy Act added additional protections to consumers. The Act is broader in scope than HIPAA because it applies not only to health care providers, health plans and other entities that process health insurance claims but also to any individual, business, or organization that obtains, stores, or possesses protected health information (PHI), as well as their agents, employees and contractors if they create, receive, obtain, use or transmit PHI.

VAERS

Vaccine Adverse Event Reporting System

A National Program for Monitoring Vaccine Safety

Vaccine Adverse Event Reporting System (VAERS)



The Vaccine Adverse Event Reporting System (VAERS), is a national program managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States. VAERS collects and reviews reports of adverse events that occur after vaccination. An "adverse event" is any health problem or "side effect" that happens after a vaccination. VAERS cannot determine if a vaccine caused an adverse event, but can determine if further investigation is needed.

VAERS provides valuable information

VAERS is an early-warning system that detects problems possibly related to vaccines. The system relies on reports from healthcare providers*, vaccine manufacturers, and the general public. Reporting gives CDC and FDA important information to identify health concerns and ensure vaccines are safe in order to protect the public's health.

VAERS staff evaluate reports of adverse events

VAERS defines a "serious adverse event" as life-threatening illness, hospitalization, prolongation of an existing hospitalization, permanent disability or death. Once adverse events are identified using VAERS, they may be monitored in other immunization safety systems to confirm if a particular adverse event is related to a vaccination and identify any specific risk factors.

Anyone can report to VAERS

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, vaccine manufacturers and the general public. CDC and FDA encourage anyone who experiences an adverse event after receiving a vaccine to report to VAERS.

How to report to VAERS

You can report to VAERS online at https://vaers.hhs.gov/index.

For further assistance reporting to VAERS, visit https://vaers.hhs.gov/index or contact VAERS directly at info@VAERS.org or 1-800-822-7967.

VAERS data are available to the public

VAERS data can be downloaded at https://vaers.hhs.gov/data/index or searched at http://wonder.cdc.gov/vaers.html. Privacy is protected and personal identifying information (such as name, date of birth and address) is removed from the public data.

For more information about VAERS:

E-mail: info@vaers.org

Phone: 1-800-822-7967

Web site: www.vaers.hhs.gov

*Healthcare providers are encouraged to report all clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event. They are also required to report to VAERS adverse events found in the Reportable Events Table (RET) at https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

FACT SHEET

CS267401