Flesch-Kincaid Grade Level: 9.5

**Informed Consent/Parental Permission Form**

**Emergency Use of Jynneos Vaccine in Children to Prevent Infection from Poxviruses**

Jynneos vaccine is being offered for your child under a single-patient, emergency Investigational New Drug (IND) use (also known as “compassionate use”), authorized by the Food and Drug Administration (FDA). Your child has or may have been exposed to a poxvirus such as monkeypox virus. Please read this consent form carefully and ask any questions you/your child may have. If you choose for your child to get Jynneos, you will be asked to sign this consent form. You will receive a copy of the signed consent form to keep.

**What are poxviruses?**

Poxviruses are a family of viruses that can cause serious diseases such as smallpox, monkeypox and cowpox. These viruses can cause serious illnesses in people. Poxviruses can spread from animals to humans and sometimes from one person to another. Monkeypox (MPX) causes fever, headache, backache, and swollen lymph nodes, followed by a blister-like rash in humans. Other symptoms may develop before the rash appears which may spread and become raised bumps and pus-filled blisters (called lesions). They usually crust, scab, and fall off after about 2-4 weeks, leaving a pitted scar.

**What is Jynneos vaccine?**

Jynneos (also known as Imvamune, Imvanex, MVA-BN) is a FDA-approved vaccine for the prevention of smallpox and MPX in high-risk adults (≥18 years of age). It can be given after being exposed to the virus, known as post-exposure prophylaxis (PEP), or in adults at high risk of occupational exposure to the virus, known as pre-exposure prophylaxis (PrEP). It is currently the only FDA-approved vaccine for the prevention of MPX. It works by causing your immune system to produce its own protection (antibodies) against the virus. Although a live vaccine, Jynneos is different from traditional smallpox vaccines such as ACAM2000. Jynneos is made with a virus that is not able to spread to other parts of the body or other people (including close contacts). It can be used for vaccination in people with certain immune deficiencies or conditions.

Because the vaccine is not approved for children (<18 years ), the vaccine is being provided under a single-patient, emergency use and requires informed consent/parental permission.

**Why is Jynneos vaccine being offered?**

Your child may have been exposed to MPX virus, or your child may be at high risk for exposure to the MPX virus. Jynneos vaccine may help to prevent MPX in children who may come into contact or have been in contact with someone who has MPX or may have been exposed to MPX virus.

**What are the benefits?**

We do not know for certain if your child will benefit from Jynneos. The vaccine may help protect children from getting MPX. Adults who received Jynneos were not considered protected until 2 weeks after the second dose.

**What happens if I choose for my child to receive Jynneos?**

If you choose for your child to be vaccinated under this program, they will get the vaccine to reduce their risk of MPX infection. However, it is very important for you to know the risks and benefits of the vaccine and ask questions of your healthcare provider for any concerns you may have.

Pre-exposure Prophylaxis (PrEP)

Jynneos can be given to children at high risk for potential exposure to MPX virus **before** an exposure to an infected person or animal occurs. This would be done to help prevent illness if an exposure were to happen. The vaccination is given as **two doses given 4 weeks** **apart** (one dose at week 0 and a second dose at week 4). It is not known whether Jynneos can protect your child against monkeypox before the two dose series is complete.

Post-exposure Prophylaxis (PEP)

Jynneos can be given to children **after** an exposure to an infected person or animal with MPX. It may help prevent your child from disease or make it less severe. The vaccination is given as **two doses given 4 weeks** **apart**. The ability of Jynneos to be able to protect your child after they have been exposed to MPX virus is unknown.

**How is Jynneos vaccine given?**

Your child will receive an injection under the skin (not in muscle), preferably in the upper arm. Children less than 1 year of age will receive the vaccination under the skin on their thigh muscle.

Your child will be monitored for about 30 minutes after the vaccination to make sure there are no side effects. You should report any side effects to your healthcare provider as soon as possible, including after your return home and in the following weeks.

Children will need to return **4 weeks after the first dose to receive their second and final dose of Jynneos vaccine**.

**What are the risks/side effects of Jynneos?**

Information on side effects is from healthy adults with and without previous history of smallpox vaccination. Most commonly reported side effects include:

|  |  |  |
| --- | --- | --- |
| * pain, redness, discoloration, swelling, hardening, bruising, small bump, or itching at shot site | * muscle pain | * joint pain |
| * tiredness | * nausea |
| * headache | * extremity pain | * change in appetite |
| * fever | * chills |  |

The number of side effects among adults with HIV infection and adults with atopic dermatitis was similar to those observed in healthy adults. Therefore, it may be reasonable to anticipate similar side effects among children.

A list of side effects can also be found in the [Jynneos Package Insert](https://www.fda.gov/media/131078/download).

If your child experiences serious side effects, please contact your healthcare provider as soon as possible. You can also report any side effects online at <https://vaers.hhs.gov/reportevent.html>.

**Who should not get Jynneos?**

If your child has not been exposed to MPX and is not at risk of becoming ill with MPX, or your child is not at high-risk of possible exposure to MPX, they may not need Jynneos. Speak to your healthcare provider if they have a fever, allergy to egg or chicken proteins, allergy to antibiotics such as gentamicin or ciprofloxacin, or tromethamine). Children with weak immune systems, including those receiving immunosuppressive therapy, can receive Jynneos, but may have a weaker immune response to the vaccine.

**What other choices do I have instead of Jynneos?**

Another vaccine, ACAM2000, is FDA-approved to prevent smallpox disease for persons at high risk for smallpox infection including children and adults. ACAM2000 is also available under a CDC-sponsored expanded access IND protocol for PEP use of ACAM2000 for MPX in adults and children. ACAM2000 is effective at protecting people against poxvirus when given before your child is in contact with another person or animal that has a poxvirus infection. Vaccination with ACAM2000 after exposure to MPXV may help prevent your child from disease or make it less severe. Because ACAM2000 vaccine virus is a live virus that replicates, it can spread to other parts of the body and to other people if you do not care for the vaccination site properly. If the virus is spread to someone with health problems, it can cause serious illness. Additionally, some people with skin or immune system problems may have uncontrolled spread of the vaccine virus to other parts of their body. Some people have experienced serious heart problems after vaccination with ACAM2000. Talk to your healthcare provider if you have questions about which vaccine may be right for your child.

If your child has been exposed to a person or animal with MPX, you should closely monitor them for any symptoms of MPX such as fever, muscle aches, headache, and rash. If they develop MPX symptoms or symptoms that are concerning to you, you should seek medical care and isolate them from others. There are no FDA-approved drugs to treat MPX. Two drugs are FDA-approved for treatment of smallpox (tecovirimat and brincidofovir). Although they don’t have an FDA-approval for MPX, tecovirimat is available under a CDC-held expanded access IND protocol (compassionate use) to treat monkeypox. Vaccinia Immune Globulin Intravenous (VIGIV) is approved by FDA for treatment of complications from smallpox vaccine. Use of VIGIV for treatment of MPX is also available under a CDC-held expanded access IND protocol. You should talk to your healthcare provider about any questions you may have on treatment options that may be available.

**What if I decide for my child not to get vaccinated with Jynneos?**

It is your choice for your child to be vaccinated or not. You can decide for your child not to continue the vaccine dose series at any time. However, one dose of vaccine is not expected to provide protection. If you do not want your child to be vaccinated against MPX and they are exposed to the MPX virus, they might develop MPX that may lead to serious illness. Your child should avoid contact with anyone who has MPX.

**What if my child is pregnant, breastfeeding or may become pregnant?**

Jynneos may involve risks to pregnant people or to the embryo or fetus of a person who may become pregnant. There is not enough data on the safety of Jynneos in pregnant persons. It is not known whether Jynneos is excreted in human milk or what the impact of Jynneos is on milk production. Talk to your healthcare provider if your child is pregnant or breastfeeding to decide whether they should receive Jynneos.

**What are the costs?**

Jynneos is provided at no cost. Choosing to get the vaccine should not affect any health insurance that you have. This includes private insurance, Medicare, or Medicaid you use for routine medical costs not related to this program.

**What about my privacy?**

We will keep all facts about you and your child private to the extent allowed by applicable law. People who work for CDC, FDA, U.S. Department of Health and Human Services, local/state health authorities, and the vaccine manufacturer, may look at your child’s information related to Jynneos administration, including their name and personal information, to ensure and monitor the appropriate and safe use of Jynneos. If this information is shared with anyone else, your and your child’s name and personal information will not be used or listed. This includes reports or any publications such as articles in scientific journals. We may contact you using the contact information you provided to follow-up with you on how your child is doing.

**What if your child is harmed or have problems or questions?**

If your child is harmed as a result of being in this program, they will be treated. You or your insurer, Medicare, or Medicaid will have to pay for their care. If you have questions or feel your child was harmed as a result of participation in this program, please contact your healthcare provider who administered the vaccine.

Name of Healthcare Provider: Phone #:

**Written Informed Consent:**

I have read this form, or it has been read to me. I have had a chance to ask questions and they were answered. I agree for my child to get Jynneos vaccine. I have been given a copy of this consent form. I have been told that I and my child will not lose any legal rights by being in this program.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | | | | |
| Child’s Name (Printed) |  | Child’s Date of Birth (mm/dd/yy) | | | | |
| Parent/Legal Guardian’s Name (Printed) |  | Signature of Parent/Legal Guardian | |  | | Date | | |
| Printed Name of Person Conducting Consent Interview |  | Signature of Person Conducting Consent Interview |  | | Date | | |

**Translator Documentation (if applicable)**

*Translator to document if informed consent process was given in another language other than English.*

|  |
| --- |
|  |

|  |  |  |
| --- | --- | --- |
| Name of Translator |  | Language |
| Signature of Translator |  | Date |