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RETIRED
Effective Date: 12/03/2020

Jynneos™ (smallpox and monkeypox, live, non-replicating vaccine)

FDA approval: September 24, 2019

HCPCS: J3490

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved age
 - b. FDA approved indication

- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: FDA approved dosing
 - b. Initial Authorization Period: 2 months with no renewal allowed

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

- A. **FDA approved indication / Diagnosis**
 - a. For the 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

**Please refer to most recent prescribing information.*

- B. **Background Information**
 - a. Smallpox
 - i. Smallpox is a highly contagious and deadly disease, which was eradicated worldwide by 1980 after a global vaccination campaign and no longer occurs naturally

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- ii. Unique to humans, the disease is caused by the variola virus and is transmitted from person to person through direct contact with contaminated fluids and objects, as well as through the air
 - iii. Historically, about 30% of those who became infected with smallpox died from the illness
 - iv. Despite being eradicated, smallpox is considered by many governments to be a significant bioterrorism threat and as routine vaccination stopped in the 1970's, the majority of the world's population today are highly vulnerable
 - v. Re-emergence of smallpox could occur as result of deliberate or accidental release of samples that are kept for research purposes or may be synthesized in a lab
- b. Monkeypox
- i. Monkeypox is a rare viral zoonotic disease (transmission from animals to humans) similar to human smallpox, whose causative agent, variola virus, is also a member of the Orthopoxvirus genus
 - ii. Monkeypox infection is less transmissible human-to-human than smallpox and also less deadly with case fatality estimates for monkeypox up to 10%
 - iii. Until recently, infections of monkeypox in humans had mostly been limited to central and western regions of Africa where the virus is naturally occurring
 - iv. However, during the ongoing monkeypox outbreak in Nigeria, increased human-to-human transmission has been observed and the wide geographic spread, predominantly in urban areas, has raised concerns over the disease
 - v. It is estimated that more than five million people travel to countries affected by monkeypox in Central Africa each year, suggesting a market potential for a monkeypox vaccine for travelers
- c. According to the Centers for Disease Control and Prevention (CDC), routine vaccination against smallpox in the U.S. ended in the 1970's; however, for specific populations at high risk of occupational exposure to orthopoxvirus, vaccination may be warranted
- d. Routine vaccination should be given to laboratory personnel directly handling cultures, or animals infected with replication-competent vaccinia virus, recombinant vaccinia viruses derived from replication-competent vaccinia strains, and other orthopoxviruses that can infect humans.
- e. Routine vaccination should be offered but is not routinely recommended for healthcare personnel who currently treat or anticipate treating patients with vaccinia virus infections, and for health care professionals who administer ACAM2000
- f. Prevention strategies for monkeypox include avoiding contact with animals that could harbor the virus, avoiding contact with any materials that have been in contact with a sick animal, isolating infected patients from others who could be risk for infection, practicing good hand hygiene, and using personal protective equipment when caring for patients
- g. The current guidelines have yet to be updated to include Jynneos

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

- a. Administer two 0.5 mL doses 4 weeks apart preferably in the upper arm
- b. Allow the vaccine to thaw and reach room temperature before use. Once thawed, the vaccine may be kept at 2°C - 8°C (36°F - 46°F) for 12 hours

**Please refer to most recent prescribing information.*

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F. How supplied

- a. 0.5 mL in a single-dose vial

References:

1. Jynneos [package insert]. Kvistgaard, Denmark: Bavarian Nordic A/S; December 2019.
2. ACAM2000 [package insert]. Gaithersburg, MD: Emergent Product Development Gaithersburg Inc.; March 2018.
3. Centers for Disease Control and Prevention. Smallpox. Available at: <https://www.cdc.gov/smallpox/clinicians/vaccines.html>. Accessed on October 9, 2019.
4. Centers for Disease Control and Prevention. Monkeypox. Available at: <https://www.cdc.gov/poxvirus/monkeypox/index.html>. Accessed on October 9, 2019.
5. FiercePharma. Bavarian Nordic score FDA nod for smallpox and monkeypox vaccine Jynneos. Available at: <https://www.fiercepharma.com/vaccines/bavarian-nordic-scores-fda-nod-for-smallpox-and-monkeypox-vaccine-jynneos>. Accessed October 9, 2019.

Policy History		
#	Date	Change Description
1.1	Effective Date: 12/03/2020	Policy to be retired as drug is not managed with prior authorization
1.0	Effective Date: 12/05/2019	New full drug review

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*