

# JYNNEOS Vaccine Fact Sheet

Refer to EZIZ's [Monkeypox Vaccination Resources](#) for additional clinical, billing, and administration guidance.

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| <b>Brand Name and Manufacturer</b>              | JYNNEOS™/Imvamune/Imvanex<br>(Smallpox/Monkeypox Vaccine, Live, Non-replicating) Bavarian Nordic A/S  |
| <b>NDC</b>                                      | 50632-001-02 (carton) and 50632- 001-01 (vial)  |
| <b>Indication(s) and Intended Population(s)</b> | Indicated for prevention of smallpox or monkeypox disease for these populations if patient is determined to be at high risk for smallpox or monkeypox infection: <ul style="list-style-type: none"> <li>• 18 years and older: <ul style="list-style-type: none"> <li>○ FDA-approved as a two-dose series administered subcutaneously</li> <li>○ EUA for intradermal administration</li> </ul> </li> <li>• Under 18 years: Authorized under EUA as a two-dose series administered subcutaneously (see <a href="#">press release</a>).</li> </ul> |
| <b>Dosing Regimen or Schedule</b>               | 2-dose vaccine series (full protection is anticipated 2 weeks following 2 <sup>nd</sup> dose)   |
| <b>Minimum Intervals</b>                        | 28 days apart; doses administered up to 4 days early are considered valid   |
| <b>Warning and Precautions</b>                  | <b>Severe Allergic Reactions:</b> Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS.<br><b>Altered Immunocompetence:</b> Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.  |
| <b>Screening &amp; Consent</b>                  | <b>For adults:</b> No consent form required; optional screening form available <a href="#">here</a> .   |
| <b>Post-Exposure Prophylaxis (PEP)</b>          | The sooner an exposed person gets the vaccine, the better. CDC recommends that vaccine be given within 4 days from date of exposure to prevent onset of disease. If given between 4–14 days after date of exposure, vaccination may reduce symptoms of disease, but may not prevent the disease.  |
| <b>Efficacy</b>                                 | Efficacy of JYNNEOS to prevent monkeypox is inferred from seroconversion and immunogenicity that is noninferior as compared with replicating orthopoxvirus vaccines.  |
| <b>Administration</b>                           | <b>Subcutaneous (SC):</b> Administer 0.5 mL; allow vaccine to thaw and reach room temperature before use (see <a href="#">package insert</a> ). <b>Alternative intradermal (ID):</b> Administer 0.1 mL (one-fifth of standard subcutaneous dose), preferably to inner side of the forearm, per EUA.   |
| <b>Adverse Reactions</b>                        | Injection site reactions. Some local adverse events more common after intradermal dosing: erythema (81.4% SC vs 99.5% ID), induration (69.5% SC vs 99.5% ID). Pain at injection site more common after subcutaneous dosing (91.0% SC vs 65.4% ID).  |
| <b>PPE</b>                                      | Standard for immunization   |
| <b>Reconstitution</b>                           | Do not dilute   |
| <b>Dosing Volume</b>                            | <b>Subcutaneous (SC):</b> 0.5 mL each dose (1 vial); <b>intradermal (ID):</b> 0.1 mL each dose (one-fifth of vial)  |
| <b>Packaging</b>                                | (20) 0.5 mL vials ( <a href="#">see image</a> ); ancillary supplies are not provided with vaccine   |

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| <b>Storage: Unpunctured Vials</b> | Shipped at -20°C and requires cold chain management; store frozen at -25°C to -15°C (-13°F to +5°F) until expiration date on vial label (or <a href="#">lookup here</a> ) or at 2-8°C for up to 8 weeks (this differs from the package insert – see <a href="#">Provider Letter</a> )             |
| <b>Storage: Punctured Vials</b>   | Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture. After thawing, the total time stored at +2°C to +8°C (+36°F to +46°F) should not exceed 12 hours. |
| <b>Use-by Limits</b>              | Once thawed, hold at +2°C to +8°C (+36°F to +46°F) for 12 hours; do not refreeze  |
| <b>ACIP Recommendations</b>       | <a href="#">MMWR Use of JYNNEOS</a> (and CDC's <a href="#">Interim Clinical Considerations</a> )  |
| <b>Package Insert</b>             | <a href="https://www.fda.gov/media/131078/download">https://www.fda.gov/media/131078/download</a>   |
| <b>Fact Sheet for HCPs</b>        | <a href="https://www.fda.gov/media/160774/download">https://www.fda.gov/media/160774/download</a>   |
| <b>VIS</b>                        | Distribute <a href="#">Vaccine Information Statement</a> before vaccination (or <a href="#">EUA Fact Sheet for Recipients &amp; Caregivers</a> for intradermal vaccination and for people <18).   |
| <b>CPT Code</b>                   | 90611 (Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use)  |
| <b>CVX Code</b>                   | 206   |