MAT Workgroup Name: Vaccine Safety and Efficacy **Date:** March 2, 2021

Question or request:

Does the Medical Advisory Team recommend that providers administer the Johnson & Johnson/Janssen vaccine to New Mexicans?

Recommendations:

The Medical Advisory Team (MAT) Vaccine Safety and Efficacy Workgroup has reviewed the relevant documents related to the Janssen Ad26.COV2.S COVID-19 vaccine as provided by the manufacturer, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control and Prevention and concurs with the conclusions that the vaccine may prevent serious or life-threatening disease and that the known and potential benefits of the product outweigh the known and potential risks of the product. Therefore, the MAT recommends:

1. For those individuals who elect to receive a vaccine, approved healthcare providers in New Mexico should administer the Janssen Ad26.COV2.S COVID-19 vaccine consistent with the Emergency Use Authorization issued by the U.S. Food and Drug Administration and the clinical guidance provided by the U.S. Centers for Disease Control and Prevention.

2. Approved healthcare providers in New Mexico who administer the Janssen Ad26.COV2.S COVID-19 vaccine should ensure that each potential vaccine recipient receives the required vaccine information sheet to allow for a well-informed decision and receives the required vaccination documentation card upon vaccination.

3. Approved healthcare providers and health systems should monitor on-going and updated guidance from U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention related to the management of vaccine supplies, which may be provided on official websites or via official email messages to pharmacies, professional associations, or state officials.

4. Within the guidance framework provided by the FDA and CDC for vaccine administration including approved age groups, contraindications and precautions, healthcare providers and health systems should offer any available vaccine to individuals seeking vaccination.

5. As soon as vaccine becomes sufficiently available so that decisions regarding vaccine selection among multiple available products can be made, evaluation of which vaccines are most effective for particular populations should be made using all available data from clinical trials and post-approval monitoring. Future decisions on the use of vaccines should not rely primarily on ease of distribution and administration. For example, if one vaccine is shown to be more effective for a higher risk population such as persons with diabetes, then the vaccine distribution plan should include a plan for specific distribution based on that knowledge.

Assessment:

1. There are several types of vaccines against COVID-19 being developed, each using different technology and immunological principles. Some types represent established methods of vaccine production, while others use new technology for which there is limited precedent.[1] Each vaccine being developed has both advantages and disadvantages for production and administration and for the creation of immunity to the virus. Different elements of the human immune system are triggered by the different vaccine types, and the immunity produced is expected to differ in strength, duration and similarity to natural immunity. The Regulatory Affairs Professionals Society has provided a website that summarizes COVID-19 vaccine technology and regulatory status.[2]

2. All currently available COVID-19 vaccines have been determined to be highly effective in preventing severe disease and death from COVID-19. Technical evaluation of COVID-19 vaccines requires consideration of the different type of vaccines. In addition, clinical trials for the available vaccines have included different populations, occurred at different phases of the pandemic and against different variant of the virus, and have studied different vaccination outcomes. Because of these factors, broad comparison of effectiveness between vaccines based on clinical trial results is discouraged.

3. The U.S. Food and Drug Administration (FDA) is responsible for the certification and licensure of new vaccines, following review of data and reports generated by clinical trials. Vaccines licensed in the United States must meet statutory and regulatory requirements for vaccine development and approval, including for quality, development, manufacture, and control. Prior to licensure, and under extraordinary conditions such as the COVID-19 pandemic, the FDA may issue an Emergency Use Authorization (EUA) for a vaccine that has been sufficiently studied in well-controlled clinical trials, making it reasonable to believe that it may prevent serious or life-threatening disease and that the known and potential benefits of the product outweigh the known and potential risks of the product.

4. Following the issuance of an EUA, the U.S. Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (CDC ACIP) develops recommendation on how to use the vaccine to control disease, and then forwards those recommendations for approval and publication by the CDC Director and the U.S. Department of Health and Human Services.

5. The vaccines against COVID-19 will be shipped to states, including New Mexico, using various distribution systems. Once received in New Mexico, vaccines will be distributed for administration according to the federally-approved state distribution and allocation plan. [3]

6. All vaccines against COVID-19 being considered for use in New Mexico will have undergone study in controlled clinical trials with ongoing safety monitoring. These clinical trials will have undergone several phases, with interim results published [4] and reviewed by the scientific community and the FDA. Full descriptions of the clinical trials and their results are available to the public through a repository website of the National Library of Medicine. [5] On-going FDA safety and effectiveness monitoring will occur for all vaccines given EUA and for vaccines that receive full FDA approval.

7. As of March 2, 2021, the FDA has issued Emergency Use Authorization [6] for the Janssen Ad26.COV2.S COVID-19 vaccine and CDC ACIP has approved its use.

8. A fact sheet and information to guide vaccine administration has been provided by the FDA for the Janssen Ad26.COV2.S COVID-19 vaccine.[7]

9. A patient information fact sheet (FAQ) for the Janssen Ad26.COV2.S COVID-19 vaccine has been developed by the FDA and its distribution to each potential vaccine patient will be required prior to administration. [8] Additional patient information material will be developed by the CDC for distribution.

10. Additional clinical guidelines for providers have been developed by the CDC that further describe vaccine procedures, special populations considerations, vaccine timing, testing after vaccination, and other clinical considerations, and that assist in differentiating post-vaccine local and systemic reactions from symptoms of COVID-19. [9, 10,11, 12]

11. The CDC has provided guidance on the addition of Janssen Ad26.COV2.S COVID-19 vaccine to the overall vaccination strategies used by states, including the use of the Janssen vaccine in individuals who are medically unable to receive a second dose of the approved mRNA vaccines, as well as overlapping contraindications and precautions between the Janssen Ad26.COV2.S COVID-19 and mRNA vaccines related to allergies and preexisting conditions.[10]

Additional considerations :

Vaccine administration, particularly for special populations, should occur via shared decision-making between the provider and recipient using informational materials provided by the FDA and CDC in order to allow for a well-informed decision based on the risks and benefits of the vaccine.

Providers administering the Janssen Ad26.COV2.S COVID-19 vaccine should carefully review the recommendations for offering vaccine to members of special populations as defined in the CDC clinical considerations [8,9], and be aware of exclusion of individuals under the age of 18 years.

Providers should be aware that the use of the Janssen Ad26.COV2.S COVID-19 vaccine is contraindicated for individuals with prior severe allergic reactions or anaphylactic reactions to injectable therapy or any vaccine. The CDC has provided guidance for the management of anaphylaxis at sites providing vaccination.[13]

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Resources/Reference:

1. CDC: Different COVID-19 vaccines: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html
2. Vaccine tracker: https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker
3. New Mexico Vaccine Plan: https://cv.nmhealth.org/covid-vaccine/
4. Sandoff J, et al. Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine. https://www.nejm.org/doi/full/10.1056/NEJMoa2034201
5. Clinical Trials.gov: https://clinicaltrials.gov/
6. FDA EUA Letter: https://www.fda.gov/media/146303/download
7. FDA Provider Fact Sheet and Prescribing Information: https://www.fda.gov/media/146304/download
8. FDA Patient Fact Sheet: https://www.fda.gov/media/146305/download
9. CDC Clinical Guidance: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
10. CDC What clinicians need to know: https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf
11. CDC Post-vaccine considerations for HCP: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html
12. CDC Post-vaccine considerations for residents of long-term care facilities: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html
13. CDC Interim considerations for the management of anaphylaxis: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html