MAT Workgroup Name: Vaccine Safety and Efficacy **Date:** December 20, 2020

Question or request:

Does the Medical Advisory Team recommend that providers administer the Moderna mRNA-1273 vaccine to New Mexicans?

Recommendations:

The Medical Advisory Team (MAT) Vaccine Safety and Efficacy Workgroup has reviewed the relevant documents related to the Moderna mRNA-1273 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 Moderna mRNA-1273 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 Moderna mRNA-1273 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.

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. 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. Technical evaluation and comparison of COVID-19 vaccines requires considerations of the types of vaccines and the expected differences. The Regulatory Affairs Professionals Society has provided a website that summarizes COVID-19 vaccine technology and regulatory status. [1]

2. 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.

3. 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.

4. 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. [2]

5. 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 [3] 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. [4] On-going FDA safety and effectiveness monitoring will occur for all vaccines given EUA and for vaccines that receive full FDA approval.

6. On December 18, 2020, the FDA issued Emergency Use Authorization [5] for the Moderna mRNA-1273 vaccine and CDC ACIP has also approved its use.

7. A fact sheet and information to guide vaccine administration has been provided by the FDA for the Moderna mRNA-1273 vaccine.[6]

8. A patient information fact sheet (FAQ) for the Moderna mRNA-1273 vaccine has been developed by the FDA and its distribution to each potential vaccine patient will be required prior to administration. [7] Additional patient information material will be developed by the CDC for distribution.

9. 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. [8,9, 10,11]

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 to allow for a well-informed decision based on the risks and benefits of the vaccine.

Providers administering the 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 Moderna mRNA-1273 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.[12]

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Resources/Reference:

1. Vaccine tracker: https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker
2. New Mexico Draft Vaccine Plan: https://cv.nmhealth.org/draft-vaccine-plan/
3. Polack, FP, et. al. "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine" in the New England Journal of Medicine: https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_home
4. Clinical Trials.gov: https://clinicaltrials.gov/
5. FDA EUA Letter: https://www.fda.gov/media/144636/download
6. FDA Provider Fact Sheet and Prescribing Information: https://www.fda.gov/media/144637/download
7. FDA Patient Fact Sheet: https://www.fda.gov/media/144638/download
8. CDC Clinical Guidance: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html
9. CDC ACIP Clinical Considerations: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/06-COVID-Mbaeyi.pdf
10. CDC Post-vaccine considerations for HCP: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html
11. CDC Post-vaccine considerations for residents: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html
12. CDC Interim considerations for the management of anaphylaxis: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html