COVID-19
PRE-EXPOSURE PROPHYLAXIS (PrEP)
PLAN

December 8, 2021

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I. PURPOSE

The purpose of the plan is to facilitate statewide preparedness for COVID pre-exposure prophylaxis (PrEP) release through the creation of a robust planning document, clear communication between participating departments within the State of New Mexico, timely dissemination of information to healthcare providers, and clear education of the public regarding pre-exposure prophylaxis. Please note, information regarding COVID-19 therapeutics is limited at this time. The plan will continue to evolve as additional information is received.

II. BACKGROUND

Evusheld (tixagevimab co-packaged with cilgavimab), has received emergency use authorization (EUA) for pre-exposure prophylaxis (prevention) of COVID-19. Evusheld is a combination of two long-acting monoclonal antibodies given intramuscularly every 6 months. The product is authorized for adults and pediatric patients (12 years of age and older weighing at least 88 pounds (40 kilograms). Patients must not be currently infected with COVID-19 or had recent known exposure to a person infected with COVID-19. Individuals must either have:

- moderate to severely compromised immune systems due to a medical condition or due to taking immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination OR
- a history of severe adverse reactions to a COVID-19 vaccine and/or component(s) of those vaccines, therefore vaccination with an available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended.

Vaccines remain the best way for the vast majority of people to protect themselves against severe illness and hospitalization from COVID-19. Patients with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccine. Evusheld should be administered at least 2 weeks after COVID-19 vaccination.

For more information, providers should refer to the *Fact Sheet for Healthcare Providers: Emergency Use Authorization for Evusheld* https://www.fda.gov/media/154701/download

Evusheld is not immediately available. The federal government will be allocating the product. New Mexico will be receiving an initial supply of 312 doses for the first 2-week cycle. Distribution will begin in the next 5-10 days.

III. LIMITED PROVIDER NETWORK

Due to high case rates (currently around 1,200 new cases per day) and limited supply (312 doses for the initial 2-week cycle), the provider network for COVID PrEP will be limited to the following specialists: HIV/AIDS care, transplant services, oncology, hematology, rheumatology, neurology, gastroenterology, and allergy/immunology. As the supply increases, long-term care pharmacies will also receive allocations to ensure access to COVID PrEP in nursing facilities across the state.
Primary care providers treating an immunocompromised patient or patient with vaccine contraindication shall refer the patient to a COVID PrEP provider for treatment. A list of COVID PrEP providers can be obtained by emailing COVID.Therapeutics@state.nm.us.

In rare cases when an immunocompromised patient is unable to be referred to a COVID PrEP provider due to extenuating circumstances, the primary care physician may fill out a waiver form to receive a dose of COVID PrEP. The waiver is subject to review and approval by the Department of Health COVID therapeutics team. The waiver form may be obtained by emailing COVID.Therapeutics@state.nm.us.

IV. ENSURING HEALTH EQUITY

The Department of Health will send targeted text and email notifications regarding the availability of COVID PrEP to patients who have indicated they are immunosuppressed during vaccine registration. Demographic groups with health disparities during the COVID response will receive targeted communications first.

V. SCREENING OF PATIENTS

Due to limited supply, screening of patients is recommended to facilitate appropriate use.

RECOMMENDED SCREENING FOR IMMUNOCOMPROMISED PATIENTS

Negative IgG SARS-CoV-2 antibody assay following a full course of vaccination

Despite reduced SARS-CoV-2 vaccine response rates in in some immunocompromised patients, vaccination is recommended for all immunocompromised patients regardless of the underlying cause of the immunodeficiency.

While COVID PrEP remain severely limited, restricting prescribing to fully vaccinated, immunocompromised patients who lack an antibody response to SARS-CoV-2 spike or to the receptor binding domain is likely to provide access to treatment to those at the highest risk of acquiring severe or fatal COVID-19. If a laboratory offers multiple tests for COVID-19 antibodies, testing should be performed using the test for IgG spike or RBD antibodies rather than for nucleocapsid antibodies, since vaccines do not contain nucleocapsid antibody.

The appropriate test include: TriCore test number COVIGG, Labcorp test number 164055 and Quest test number 34499.

RECOMMENDED SCREENING FOR PATIENT WITH A CONTRAINDICATION TO VACCINE

Clear documentation that vaccination is contraindicated

The CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:

1. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
    a. A patient with an allergic reaction to a mRNA vaccine may be able to receive Janssen COVID-19 vaccine and vice versa.
2. Known diagnosed allergy to a component of the COVID-19 vaccine.

Please refer to the CDC clinical considerations for guidance regarding contraindications and precautions.
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications