April 20, 2022

TO: Marin Healthcare Providers

RE: COVID-19 Therapeutics | Paxlovid (ritonavir-nirmatrelvir)

Background

The Food and Drug Administration (FDA) has authorized emergency use of oral antiviral medications for COVID-19. Among these, Paxlovid is a preferred agent currently, based on increasing supply and efficacy in preventing hospitalizations among high-risk patients. This advisory outlines clinical criteria for Paxlovid treatment and the means for providing this medication to eligible patients in Marin County.

Prescribing Protocol

1. Prescribing providers should confirm patient eligibility. Many patients with active COVID-19 infection do not meet criteria for Paxlovid therapy based on treatment risk and benefits.

2. Patients should be in one of the following treatment categories:
   a. Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status. See list below for Immunocompromising Conditions and Treatments
   b. Unvaccinated or unboosted individuals at the highest risk of severe disease.
   c. Age ≥65 years.
   d. Age <65 years with at least one CDC-defined Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19. See list below.

3. Prescribing providers must confirm:
   a. Patient is a resident of Marin County; and,
   b. Patient must have an active COVID-19 infection, confirmed by a positive rapid antigen or molecular test after testing for symptoms or for known exposure to a probable or confirmed case; and,
   c. Patient should be provided treatment within 5 days of symptom onset.

4. Provider should review the FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR PAXLOVID.

5. Provider must review contraindications, warnings and precautions, adverse reactions, and drug interactions with patients:
   a. Paxlovid is anti-retroviral therapy with significant drug-drug interactions. Consultation with a clinical pharmacist and the Liverpool COVID-19 Drug Interactions website should be considered.

6. Providers who have patients with mild to moderate COVID-19 who meet criteria for treatment with Paxlovid should submit prescriptions to Golden Gate Pharmacy. Patients who require emergency care due to severity of symptoms should be referred to the emergency room for evaluation.
a. Golden Gate Pharmacy – Delivery will not be made until the pharmacy has received the E-script; completed online form; and notified the patient.
   i. Hours: Monday thru Friday 9 – 5 pm (Orders received over the weekend will be processed on Monday)
   ii. Delivery Only - Patients should NOT pick up from the pharmacy (no charge for delivery). Deliveries will be made in North, South, and Central Marin, and as far west as Fairfax.
   iii. Providers only can complete online form (passcode MAC2022) to attest to the prescription.
   iv. After submitting the request, a pharmacy staff member will contact you within one business day to confirm the product is available for the patient.
   v. If you have not heard from the pharmacy within one day of submitting the request, call GGP at (415) 455-9042.

7. As supplies continue to increase, additional pharmacies will furnish Paxlovid, including national chain pharmacies. The COVID-19 therapeutics locator will display the most current locations.

Immunocompromising Conditions and Treatments List

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell therapy or hematopoietic cell transplant (HCT) Within 2 years of transplantation OR on immunosuppressive therapy
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection:
  - HIV and CD4 cell counts <200/mm3
  - History of an AIDS-defining illness without immune reconstitution
  - Clinical manifestations of symptomatic HIV
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day for ≥ 2 weeks); alkylating agents; antimetabolites; transplant-related immunosuppressive drugs; cancer chemotherapeutic agents classified as severely immunosuppressive; tumor necrosis factor (TNF) blockers; or other biologic agents that are immunosuppressive or immunomodulatory

CDC-defined Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19

- Cancer
- Cerebrovascular disease
- Chronic kidney disease
- Interstitial lung disease
- Current pulmonary embolism
- Pulmonary hypertension
- Bronchopulmonary dysplasia
- Bronchiectasis
- COPD
- Cirrhosis
- Non-alcoholic fatty liver disease
- Alcoholic liver disease
- Autoimmune hepatitis
- Diabetes mellitus, type 1 and type 2
- Congestive heart failure
- Coronary artery disease
- Cardiomyopathy
- Mood disorders - including depression, Schizophrenia spectrum disorders
- Obesity (BMI >= 30 kg/m2)
- Pregnancy
- Smoking
- Active Tuberculosis
- Social determinants of health, which may include but are not limited to: unstable housing, poverty or food insecurity, single head of household in minimum wage employment, non-English speaking immigrant, active substance use disorder.