



## Message from San Mateo County's Health Officer Regarding the Eligibility Criteria and Prescribing Protocol for the Treatment of COVID-19 with Paxlovid

May 31, 2022

Thank you for all you have done and continue to do for our community during this pandemic! I want to encourage providers and healthcare systems to improve the use of, and access to, COVID-19 therapeutics, particularly Paxlovid, especially during our current surge.

Please take some time to identify and remove barriers to prescribing and accessing these medications. For healthcare systems, this means making it easier on providers to prescribe through electronic health records (EHRs) or even automating parts of the process. From what I can tell, Kaiser has identified and implemented a number of best practices in this regard.

The Food and Drug Administration (FDA) has authorized emergency use of three (3) antiviral medications for outpatient treatment of mild to moderate COVID-19 illness in certain people who are at higher risk for severe disease: Nirmatrelvir/Ritonavir (Paxlovid), Molnupravir (Lagevrio), and Bebtelovimab. Based on increasing supply, ease of administration, and [89% efficacy in preventing severe illness and death](#) compared to placebo, Paxlovid is currently preferred. Of note, Sotrovimab is no longer authorized due to decreased efficacy in the setting of the Omicron variant of COVID-19.

### Eligibility Criteria and Prescribing Protocol

1. Prescribing providers should confirm patient eligibility. To be eligible, patients should:
  - a. Have a positive SARS-CoV-2 test (confirmation of a positive home rapid SARS-CoV-2 test result with additional direct SARS-CoV-2 testing is not required), and
  - b. Present within 5 days of onset of symptoms consistent with COVID-19, and
  - c. Be well enough to qualify for outpatient treatment at time of presentation, and
  - d. Be  $\geq 18$  years old OR  $\geq 12$  years old AND weigh at least 88 pounds (40 kg), and
  - e. Have one or more risk factors for progression to severe COVID-19 disease (see below), and
  - f. Have no known or suspected severe renal impairment (eGFR  $< 30$  mL/min), severe hepatic impairment (Child-Pugh Class C), or clinically significant hypersensitivity reactions [e.g., toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome] to the active ingredients (nirmatrelvir or ritonavir) or other components of the product.
2. Providers should review the [Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid](#).
3. Providers should review contraindications, warnings and precautions, adverse reactions, and drug interactions with patients:





- a. Paxlovid has significant [drug-drug interactions](#). Consultation with a clinical pharmacist and the [Liverpool COVID-19 Drug Interactions](#) website should be considered.
4. The [COVID-19 therapeutics locator](#) displays locations that are currently stocking and dispensing Paxlovid and other COVID-19 antivirals.
5. Patients who require emergency care due to severity of symptoms should be referred to the emergency room for evaluation.

### **Risk factors for progression to severe COVID-19 disease:**

#### Immunocompromising Conditions and Treatments

- 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/mm<sup>3</sup>
  - 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  $\geq$  30 kg/m<sup>2</sup>)
- 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.

#### **Additional Resources**

- [FDA PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers](#)
- [Liverpool COVID-19 Drug Interactions website](#)
- [Fact Sheet for Healthcare Providers Emergency Use Authorization for Paxlovid](#)
- NIH Guidance [The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Non-hospitalized Patients with Mild to Moderate COVID-19](#)
- NIH Guidance [The COVID-19 Treatment Guidelines Panel's Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints](#)

Thank you for continuing to partner with us.

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Dated: May 31, 2022

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San Mateo County Health Officer