



COUNTY OF SAN LUIS OBISPO HEALTH AGENCY
PUBLIC HEALTH DEPARTMENT
PROVIDER HEALTH ADVISORY

Date: December 7, 2022

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Updates from CDPH—Reminder to Lower Barriers to Prescribing COVID-19 Therapeutics to Mitigate Impact of COVID-19

The California Department of Public Health has shared the attached [health advisory](#) to remind providers that:

- Any patient with suspected COVID-19 should be tested for SARS-CoV-2 infection and all symptomatic patients with a positive COVID-19 test of any type should be evaluated for treatment with one of the NIH recommended treatment options. Currently, the primary outpatient treatment options are nirmatrelvir/ritonavir (Paxlovid) and remdesivir.
- There is ample supply of COVID-19 therapeutic agents, but they have been underused—especially among populations disproportionately impacted by COVID-19, including communities of color, low-income communities, and residents of long-term care facilities.
- **Providers should have a low threshold to prescribe COVID-19 therapeutics** given the broad range of individuals who are at higher risk for severe COVID-19 (those of racial minorities, those with common medical conditions, older adults) and the benefits of treatment (possibly shortening isolation, reducing severity and duration of symptoms, preventing hospitalization, death, and potentially reducing risk of long COVID).
- Do not withhold COVID-19 treatment if the patient hasn't had recent renal or liver function tests done (the FDA EUA does not require assessment of laboratory results).
- The decision to not prescribe COVID-19 treatment should be reserved for situations in which the risk of prescribing *clearly* outweighs the benefits of treatment.

For more detail on these specific recommendations for health care providers, please see the attached advisory.

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GAVIN NEWSOM
Governor

December 2, 2022

TO: California Healthcare Providers

SUBJECT: HEALTH ADVISORY: Reminder to Lower Barriers to Prescribing COVID-19 Therapeutics to Mitigate Impact of COVID-19

Background

Currently, COVID-19 cases and hospitalizations are increasing in California. Importantly, other viruses such as influenza and Respiratory Syncytial Virus (RSV) are also circulating, affecting vulnerable populations including children and the elderly, and straining the state's healthcare systems. The U.S. Centers for Disease Control (CDC) and California Department of Public Health (CDPH) recommend that everyone 6 months of age or older has an annual influenza vaccine and stays up to date with COVID-19 vaccines, including the bivalent booster that is available for everyone over 5 years old.

Summary

Once an individual is diagnosed with COVID-19, early treatment with COVID-19-specific agents is the only existing strategy to markedly decrease risk of serious illness and prevent hospitalization. Hospitalizations from COVID-19 are still having marked impact on patients and communities, and preventing serious illness is core to ongoing planning and policy. We should optimize all of our tools to decrease the hospitalizations, deaths, and long term impacts of COVID-19 as it still causes significant preventable morbidity and mortality. There is **ample supply of COVID-19 therapeutic agents, but they have been underused – especially among populations disproportionately impacted by COVID-19**, including communities of color, low-income communities, and residents of long-term care facilities. Studies have shown that:

- COVID-19 treatments reduce the risk for hospitalization and death by 50-88% among unvaccinated people and by **45–50% among vaccinated or previously infected people.**^{1,2,3}
- Early evidence suggests COVID-19 treatment may decrease the risk of developing post-COVID symptoms.^{4,5,6,7} The extent and scale of impact that long COVID may have on individual and population health are yet to be revealed and may be quite significant.
- SARS-CoV-2 viral load decreases faster among people treated compared with people not treated, suggesting the potential for decreased transmission and isolation time for test-result-based isolation protocols.¹
- Prescribing options have been shown to be safe, including in the fragile, elderly population.⁸ Risks are minimal, especially when weighed against benefits.

Lack of familiarity with new medications, navigating contraindications and drug-drug interactions, and the misperception of drug scarcity have contributed to low treatment rates, including reports of eligible patients seeking COVID-19 treatment ultimately being denied treatment.

This health alert aims to remind providers that:

- any patient with suspected COVID-19 should be tested for SARS-CoV-2 infection and
- **all symptomatic patients with a positive COVID-19 test of any type should be evaluated for treatment** with one of the NIH recommended treatment options. Currently, the primary outpatient treatment options are nirmatrelvir/ritonavir (Paxlovid) and remdesivir.

Specific Recommendations for Healthcare Providers:

- Ensure all individuals with suspected COVID-19 receive testing for SARS-CoV-2 and influenza, as appropriate, based on risk factors.
- Enable pathways for symptomatic individuals who test positive for SARS-CoV-2 and/or influenza to connect to a prescriber within 24 hours of seeking care, including new patients. Ensure all patients are aware that a new law enacted Sept 25, 2022 (PDF) requires all health plans in California to cover out-of-network care for patients seeking COVID-19 therapeutics evaluation with no cost sharing to patients.
- **Providers should have a low threshold to prescribe COVID-19 therapeutics given the broad range of individuals who are at higher risk for severe COVID-19 and can benefit from COVID-19 treatment given that:**
 1. There is evidence that patients who would benefit from treatment are not being treated.
 2. The FDA, CDC, and National Institutes for Health (NIH), include a broad range of individuals considered at higher risk for hospitalization or death from COVID-19 including:
 - Racial and ethnic minority groups
 - People who are unvaccinated or not up to date with their vaccination series against SARS-CoV-2
 - People with common conditions and behaviors such as physical inactivity, obesity, depression, smoking (former or present), and disabilities. Please see the Comprehensive CDC discussion.
 - Older adults, especially those above the age of 50 years, regardless of the presence of a medical condition.
 3. There is early, but growing, evidence that COVID-19 treatments may reduce the risk of developing long COVID.^{3,4,5,6} The extent and scale of impact that long COVID may have on population health are yet to be revealed and may be quite significant.
 4. There is ample supply of therapeutic agents, in contrast to earlier scarce supply.
 5. The potential for rebound or mild side effects does not outweigh the benefit of risk reduction for severe illness. Rebound occurs in the minority of people treated with a COVID-19 therapeutic agent,⁹ as well as people who are not treated;¹⁰ rebound is mild in >99% of cases.⁸
- Providers should prescribe COVID-19 therapeutics to the extent possible for eligible patients as noted above. **The decision to not prescribe COVID-19 treatment should be reserved for situations in which the risk of prescribing clearly outweighs the benefits of treatment in preventing hospitalization, death, and the potential for reduced risk of long COVID.**
- The following factors should **NOT** be reasons to withhold COVID-19 treatment:
 - Being fully or partially vaccinated. See risk reduction for vaccinated on page 1.
 - Having a history of prior SARS-CoV-2 infection. See risk reduction for previously infected on page 1.

- Presence of only mild disease. Patients with **mild** symptoms are, in fact, included in criteria for outpatient treatment according to the FDA EUA and NIH recommendations.
- A lack of recent renal or liver function tests. The FDA EUA does not require assessment of laboratory results.
- High risk patients co-infected with influenza and SARS-CoV-2 should receive treatment for both viruses. Co-infection is associated with more severe illness.¹¹ There are no clinically significant drug-drug interactions between the antiviral agents or immunomodulators that are used to prevent or treat COVID-19 and the antiviral agents that are used to treat influenza.

Preferred COVID-19 Treatments (listed in order of preference) are noted below. Regimens are current as of 12/1/2022. Please see NIH COVID-19 Treatment Guidelines and FDA authorization updates for the most current recommendations and regimens including updates related to subvariant susceptibilities to and revision of authorization of treatment options. Importantly, the agents below retain full activity against the current variant mix in California.

- Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid) (PDF) orally twice daily for 5 days, initiated as soon as possible within 5 days of symptom onset in people aged ≥ 12 years and weighing ≥ 40 kg; *or*
- Remdesivir (PDF) 200 mg IV on Day 1, followed by remdesivir 100 mg IV once daily on Days 2 and 3, initiated as soon as possible within 7 days of symptom onset in people aged ≥ 12 years and weighing ≥ 40 kg. Indications and dosage for outpatients < 12 years of age can be found in the remdesivir full prescribing information (PDF).

If neither of the preferred therapies for high-risk, non-hospitalized patients are available, feasible to deliver, or clinically appropriate, please see the NIH COVID-19 Treatment Guidelines outline additional options. **As of 11/30/22, the FDA has revoked EUA for bebtelovimab due to resistance of the currently circulating Omicron subvariants.** The U.S. Government recommends all product be retained in the event that SARS-CoV-2 variants susceptible to bebtelovimab, which are currently circulating at lower prevalence, become more prevalent in the future in the United States.

Nothing in this advisory is meant to contradict or supersede the FDA EUA requirements or to replace physician discretion.

Further Resources and Clinical Guidance

As the COVID-19 therapeutics landscape changes rapidly, all local health jurisdictions and medical providers are encouraged to regularly refer to the following resources for updates:

CDPH COVID-19 Therapeutics site: COVID-19 Treatments (ca.gov)

NIH COVID-19 Treatment Guidelines: COVID-19 Treatment Guidelines (nih.gov)

Health and Human Services ASPR COVID-19 Resources: COVID-19 Therapeutics | HHS/ASPR

ASPR Therapeutics Algorithm: Therapeutics Decision Aid (PDF)

ASPR Provider Information Sheet: Paxlovid Eligibility and Effectiveness (PDF)

CDPH Patient Resources: Treatment Information and Locator

CDPH Patient materials in multiple languages: Treatments Communications Toolkit

DMHC Notice on Out-of-Network Coverage for COVID-19 Care: DMHC Know Your Health Care Rights Fact Sheet (PDF)

- ¹ Hammond, Jennifer, et al. "Oral nirmatrelvir for high-risk, nonhospitalized adults with Covid-19." *New England Journal of Medicine* 386.15 (2022): 1397-1408.
- ² Ganatra, Sarju, et al. "Oral Nirmatrelvir and Ritonavir in Nonhospitalized Vaccinated Patients With Coronavirus Disease 2019 (COVID-19)." *Clinical Infectious Diseases* (2022).
- ³ Paxlovid Associated with Decreased Hospitalization Rate Among Adults with COVID-19 — United States, April–September 2022 | MMWR (cdc.gov)
- ⁴ Yan, Xie et al. Nirmatrelvir and the Risk of Post-Acute Sequelae of COVID-19." *MedRxiv* Nov 3, 2022
- ⁵ Sudre, Carole H., et al. "Attributes and predictors of long COVID." *Nature medicine* 27.4 (2021): 626-631.
- ⁶ Al-Aly, Ziyad, et al. "High-dimensional characterization of post-acute sequelae of COVID-19." *Nature* 594.7862 (2021): 259-264.
- ⁷ Peluso, Michael J., et al. "Early clues regarding the pathogenesis of long-COVID." *Trends in Immunology* (2022).
- ⁸ Zhong, Weijie, et al. "The efficacy of paxlovid in elderly patients infected with SARS-CoV-2 omicron variants: Results of a non-randomized clinical trial." *Frontiers in medicine* 9 (2022).
- ⁹ Ranganath, Nischal, et al. "Rebound Phenomenon After Nirmatrelvir/Ritonavir Treatment of Coronavirus Disease 2019 (COVID-19) in High-Risk Persons." *Clinical Infectious Diseases* (2022).
- ¹⁰ Smith DM, Li JZ, Moser C, et al. Recurrence of Symptoms Following a 2-Day Symptom Free Period in Patients With COVID-19. *JAMA Netw Open*. 2022;5(10):e2238867
- ¹¹ Swets, Maaïke C., et al. "SARS-CoV-2 co-infection with influenza viruses, respiratory syncytial virus, or adenoviruses." *The Lancet* 399.10334 (2022): 1463-1464.

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