



Updates to SNF Guidance and Therapeutics

Chandana Das, MD
Zachary Rubin, MD

Friday, May 27, 2022





Agenda

- Post Surge Dashboard change in level of concern to “high” for early alert metrics
- CDC COVID-19 Community Transmission Tracker
- Updates to the SNF guidance, in effect as of 05/25/2022
- Updates on therapeutics for COVID-19

LAC DPH Post-Surge Dashboard

- Early alert indicator for SNFs: the number of new outbreaks opened in SNFs in the previous 7 days
- On Monday, 05/23/2022, the number of outbreaks opened the week prior was 22, putting us in the high concern level.



Indicator Thresholds	Low Concern	Medium Concern	High Concern	LA County Current Values
Percent of specimens sequenced that are identified as a new Variant of Concern (including subvariants) <i>(based on the World Health Organization's designation)</i> ¹	< 10%	10%-20%	> 20%	99%
7-day average of the percent of Emergency Department (ED) encounters classified as coronavirus-related ²	< 5%	5%-10%	> 10%	5%
7-day cumulative crude case rate for the lowest income areas (30-100% area poverty) ³	< 100 per 100,000	100-200 per 100,000	> 200 per 100,000	165 per 100,000
Number of sewer systems with a two-fold or greater increase in wastewater SARS-CoV-2 concentration ⁴	0	1-2	≥ 3	0
Number of new outbreaks in skilled nursing facilities over the past 7 days ⁵	≤10	11-20	>20	22
Number of new outbreaks in TK-12 school classrooms over the past 7 days ⁵	≤ 7	8-14	≥ 15	14
Number of new outbreaks in PEH settings over the past 7 days ⁵	≤ 10	11-20	>20	13
Number of worksite cluster reports in the past 7 days ⁶	< 100	100-300	> 300	193

CDC COVID-19 Community Transmission Levels Tracker

- This is the tracker our SNFs use to determine loosening restrictions.
- Included in our SNF guidance in multiple places, as well as in the “Quick Links” section at the top of the SNF guidance webpage.
- Low, moderate, substantial, high levels.

Determining Transmission Risk ✕

If the two indicators suggest different transmission levels, the higher level is selected

	Low	Moderate	Substantial	High
New cases per 100,000 persons in the past 7 days*	<10	10-49.99	50-99.99	≥100
Percentage of positive NAATs tests during the past 7 days**	<5%	5-7.99%	8-9.99%	≥10.0%





Updates to the SNF Guidance

- Reinstating measures that were in place during the winter surge.
- Twice weekly testing for all staff and weekly testing for all residents, regardless of vaccination status.
 - Twice weekly testing can also be extended to staff members during response testing.
 - Visiting/contract staff or staff members that work less than one shift per week can be tested prior to each shift.
- N95s required for all staff that work in resident care areas or areas accessed by residents for any reason.
- Pause on all communal dining and group activities.
 - As physical therapy and rehabilitation is integral to recovery for some residents, rehab rooms may stay open with masking and social distancing.



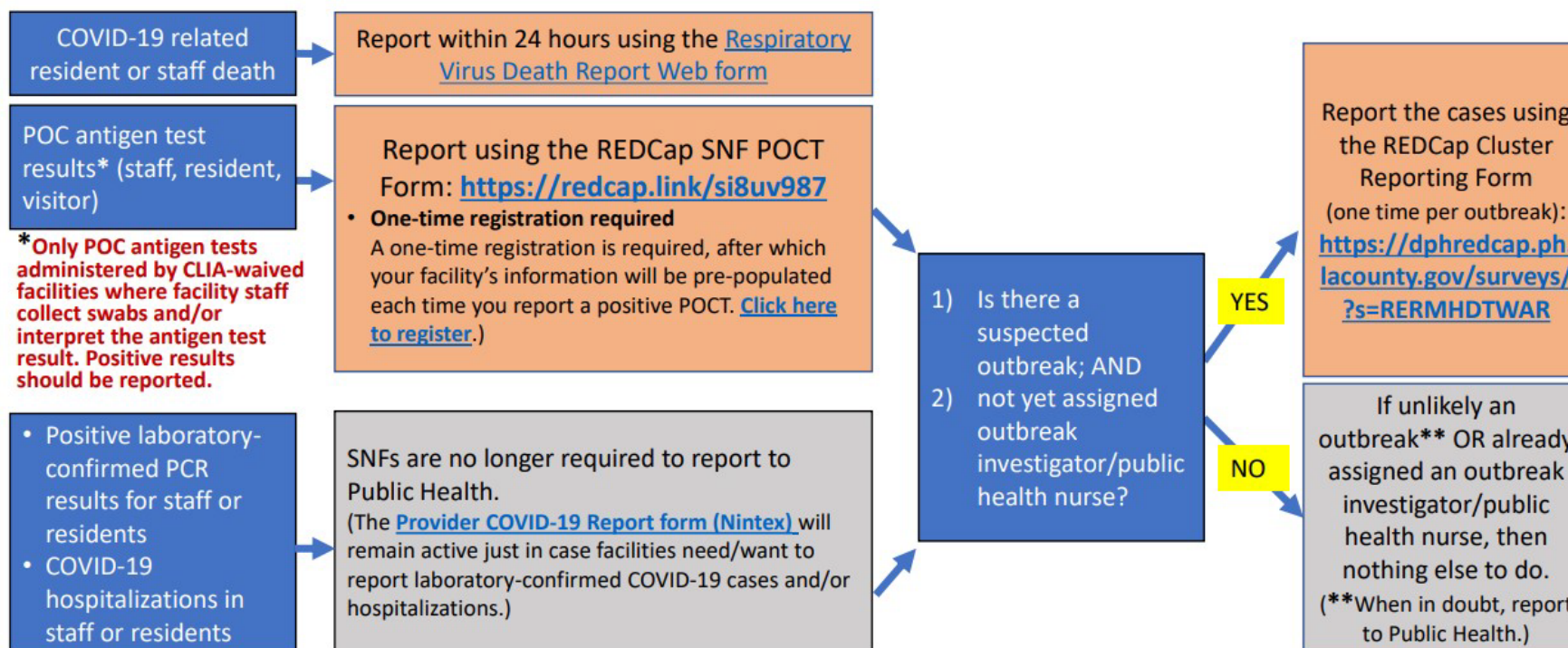
Measures that Are Not Changing

- Continue exposure and symptomatic testing as before. Continue response testing for residents as before.
- No changes to visitation, all visitors must still have a negative test to visit indoors.
- Masking still required inside the facility for staff, residents, and visitors/vendors.
- Reporting of all positive cases still required.

Reminder to Report Positive Point of Care Test Results

LAC DPH Positive COVID-19 Case Reporting Protocol for Skilled Nursing Facilities:

- LAC DPH has aligned with California State Health Officer Order [Revision of Mandatory Reporting of COVID-19 Results](#). Skilled nursing facilities (SNFs) no longer need to report individual COVID-19 cases and/or COVID-19 related hospitalizations to Public Health outside of an outbreak investigation.
- LAC DPH has aligned with CDPH's new [SARS-CoV-2 Reporting Requirements](#) for facilities with CLIA waivers. **The flowchart below describes the Public Health reporting that is still required for SNFs** (in salmon-colored boxes), which includes COVID-19 related deaths and all positive POC antigen test results.
- Any reporting requirements by CMS via the weekly NHSN survey, CDPH's SNF 123 Daily Survey, as well as timely submission of line lists to Public Health during an outbreak are separate from the changes to local Public Health reporting requirements described here.





Resources for Testing

- DHCS COVID-19 Uninsured Group Program Website for state coverage of testing for uninsured individuals.
- LAC DPH Laboratory Reference Guide.
- California Testing Taskforce Laboratory List.
- LAC DPH Guidelines for Antigen Testing in SNFs.
 - Antigen test shipment scheduled to arrive in the next few days (sometime between 05/28-05/31/2022)
 - Facilities that find they are running out of test kits can contact us at LACSNF@ph.lacounty.gov.

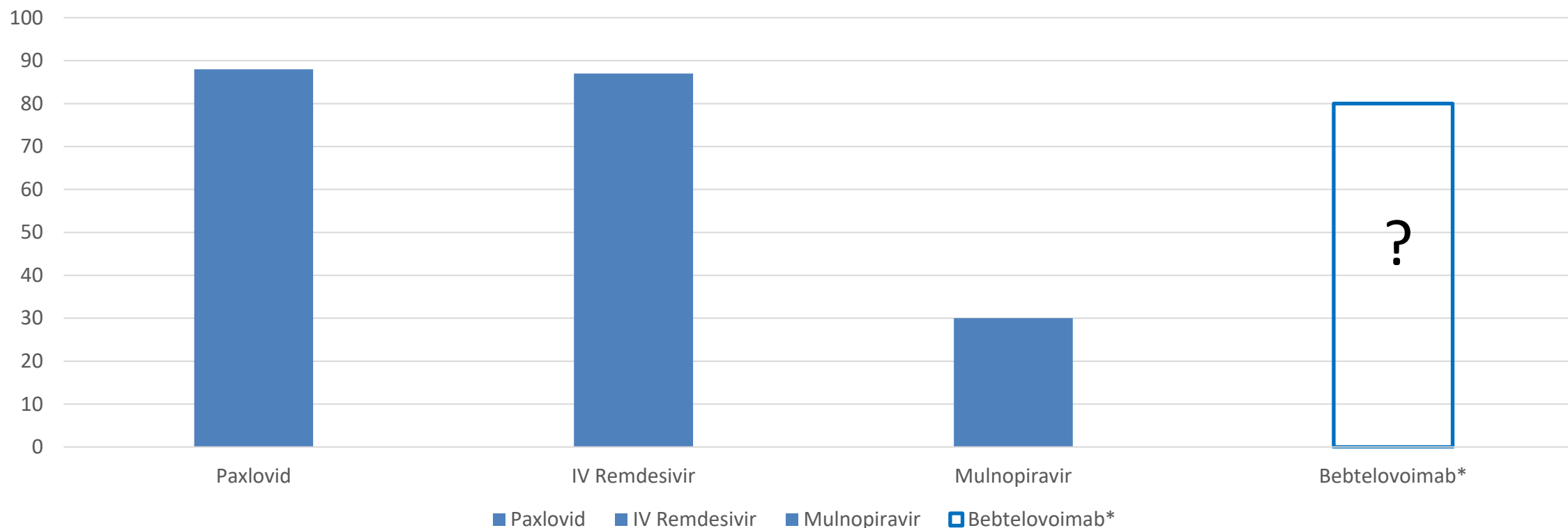


COVID-19 Therapeutics



Efficacy of therapeutics vs COVID-19 hospitalization and death

Relative efficacy vs. placebo



- <https://www.covid19treatmentguidelines.nih.gov/tables/table-3a/>
- <https://www.merck.com/news/merck-and-ridgeback-statement-on-positive-fda-advisory-committee-vote-for-investigational-oral-antiviral-molnupiravir-for-treatment-of-mild-to-moderate-covid-19-in-high-risk-adults/>
- <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-additional-phase-23-study-results>
- Gottlieb RL, Vaca CE, et al. NEJM <https://www.nejm.org/doi/full/10.1056/NEJMoa2116846>
- https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-bebtelovimab/?utm_source=site&utm_medium=home&utm_campaign=highlights

Indications for treatment or prophylaxis with mAb

Medical conditions that increase risk of poor outcomes with COVID-19 (Alla rec):

- Age >65
- Obesity (BMI>30)
- Diabetes
- Cardiovascular disease or hypertension
- Chronic lung diseases

Other conditions (BIII rec):

- Immunocompromising condition
- Obesity (BMI>25)
- Chronic kidney disease
- Sickle cell disease
- Neurodevelopmental disorder
- Pregnancy
- Medical technology-dependent (trach, vent, CPAP/BiPAP, etc)

The use of mAbs may be considered for patients with high-risk conditions and factors that are not listed in the EUAs.

CONCLUSION: Most if not all SNF/elderly residents who test positive or are exposed (e.g., during an outbreak) should be indicated for treatment/prophylaxis with mAb

Target therapies at high risk groups, regardless of vaccination status

Tier	Risk Group
1	<ul style="list-style-type: none"> Immunocompromised individuals regardless of vaccine status. Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with additional risk factors).
2	<ul style="list-style-type: none"> Unvaccinated individuals not included in Tier 1 who are at risk of severe disease (anyone aged ≥ 65 years or anyone aged < 65 years with clinical risk factors)
3	<ul style="list-style-type: none"> Vaccinated individuals at high risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with clinical risk factors) <p>Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease.</p>
4	<ul style="list-style-type: none"> Vaccinated individuals at risk of severe disease (anyone aged ≥ 65 years or anyone aged < 65 years with clinical risk factors) <p>Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease.</p>



mAb not indicated in these groups due to lack of benefit

- Hospitalized for COVID-19 (moderate or severe)
- Require O2 therapy due to COVID-19
- Chronic O2 who require increased O2 due to COVID-19.

1. <https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>

Preprint (Germany)

Table 1. SARS-CoV-2-neutralizing activity of monoclonal antibodies.

Antibody	Antibody IC ₅₀					IC ₅₀ (µg/ml)
	Wu01	Alpha	Delta	Beta	Omicron	
Bamlanivimab	0.0031	0.0043	>10	>10	>10	
Etesevimab	0.0194	0.9139	0.0019	>10	>10	
REGN10933	0.0019	0.0006	0.0009	1.8303	>10	
REGN10987	0.0094	0.0006	0.0454	0.0011	>10	
C102	0.0524	0.6460	0.0169	>10	>10	
P2B-2F6	0.1088	0.0081	>10	>10	>10	
Sotrovimab/S309	1.9642	0.1154	0.2188	0.0335	0.0950	
Fab2-36	0.1186	0.0437	0.0375	0.0987	>10	
DZIF-10c	0.0014	0.0003	2.9103	0.0326	0.0346	

IC₅₀ values >10 µg/ml indicate failure to achieve 50% neutralizing activity at the highest tested antibody concentration of 10 µg/ml.

NIH outpatient treatment hierarchy:

Preferred therapies (listed in order of preference):

- **Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid) (AIIa); or**



- **Remdesivir 200 mg (BIIa)**

Alternative therapies (for use if none of the preferred therapies are available, feasible to deliver, or clinically appropriate, listed in alphabetical order):

- **Bebtelovimab 175 mg (CIII); or**
- **Molnupiravir 800 mg (CIIa)**

NIH Treatment guidelines

Drug	Dose	Route	Age	Given by	Relative Efficacy vs placebo
Paxlovid (nirmaltrevir + ritonavir)	300mg/100mg BID x 5 days	PO	≥12 ≥40kg	Within 5 days of symptom onset	88%
Remdesivir	200mg day 1, 100mg day 2-3	IV	≥12 ≥40kg	Within 7 days of symptom onset	87%
Bebtelovimab*	175mg	IV	≥12 ≥40kg	Within 7 days of symptom onset	?
Molnupiravir*	800mg BID x 5 days	PO	≥18	Within 5 days of symptom onset	30%

*Use only if other drugs not available

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-bebtelovimab/?utm_source=site&utm_medium=home&utm_campaign=highlights



Treatment guidelines road map

COVID-19 OUTPATIENT TREATMENT GUIDELINES ROADMAP

Last Updated: May 3, 2022

This resource is intended to serve as a guide on available outpatient COVID-19 treatment options, with links to FDA Emergency Use Authorization information and guideline recommendations from national guideline-developing organizations, where available. It is not intended to endorse or otherwise promote a specific clinical recommendation or course of action. Additionally, it does not include other forms of guidance that may be available for specific subsets of populations. Finally, the guidelines referenced here may not consider local allocation and availability of scarce resources. Additional information on where to access these therapeutics can be found at the [National Infusion Center Association](#)¹⁶ and [HHS](#).¹²

Risk factors for severe COVID-19¹¹

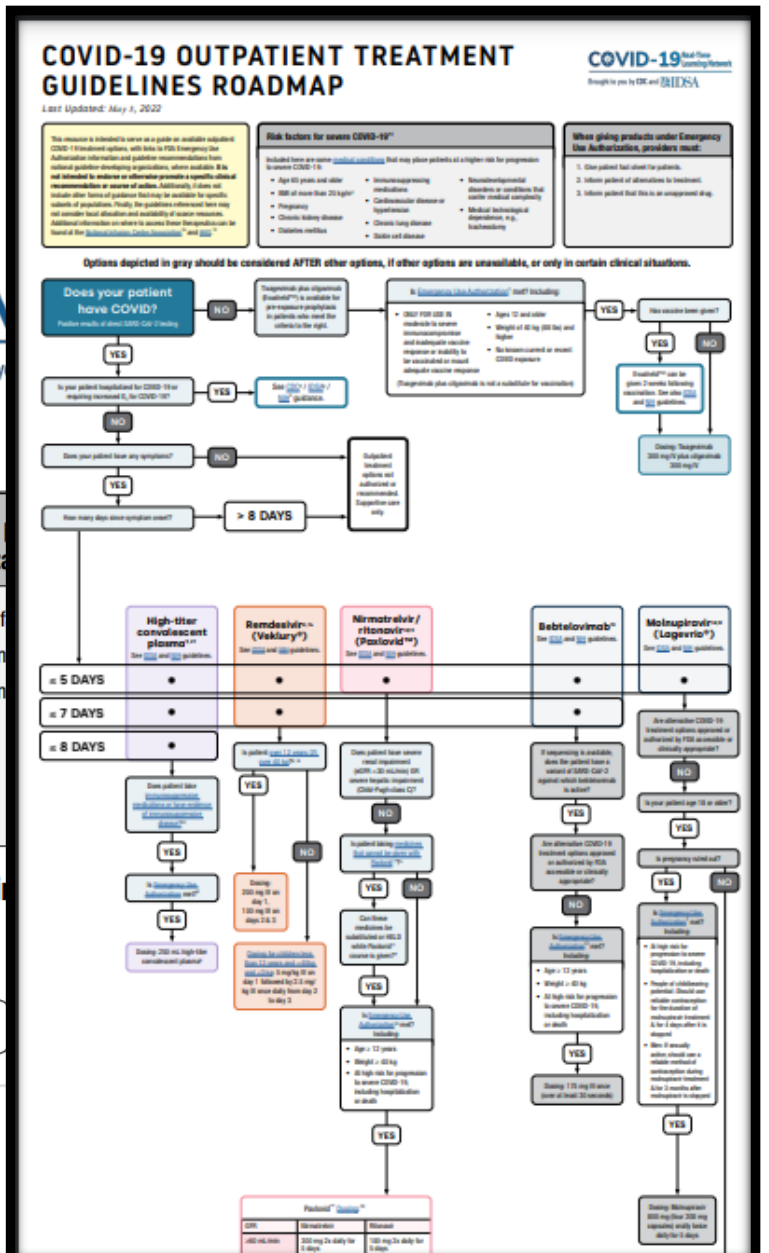
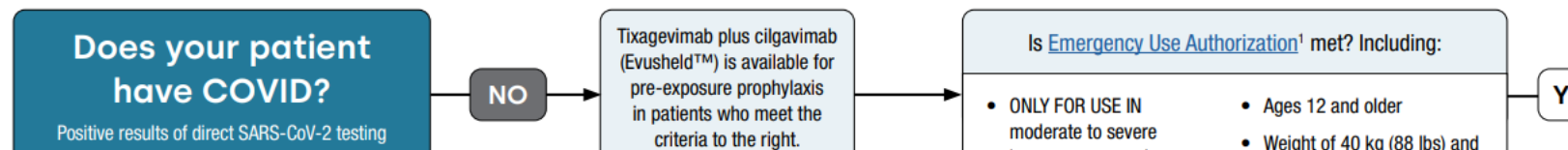
Included here are some [medical conditions](#) that may place patients at a higher risk for progression to severe COVID-19:

- Age 65 years and older
- BMI of more than 25 kg/m²
- Pregnancy
- Chronic kidney disease
- Diabetes mellitus
- Immunosuppressing medications
- Cardiovascular disease or hypertension
- Chronic lung disease
- Sickle cell disease
- Neurodevelopmental disorders or conditions that confer medical complexity
- Medical technological dependence, e.g., tracheostomy

When giving products under Emergency Use Authorization, providers must:

1. Give patient full sheet about the product.
2. Inform patient of alternatives to treatment.
3. Inform patient that this is an emergency drug.

Options depicted in gray should be considered AFTER other options, if other options are unavailable, or only in certain clinical situations.





Pre-exposure prophylaxis



Tixagevimab + Cligavimab (Evusheld)

- Combination of 2 long-acting monoclonal antibodies given IM at 2 different sites
- Dose increased to 300mg (previously 150mg)
- Age 12 and above
- Prophylactic use in people:
 - Unlikely to have good response to vaccine (severe immunocopromise: stem cell transplant, solid organ transplant, ongoing cancer therapy)
 - Those unable to receive vaccine due to documented severe hypersensitivity reaction or allergy
- Efficacy: 83% efficacy vs. symptomatic disease in interim analysis at 6 months
- DPH-Therapeutics@ph.lacounty.gov

<https://www.astrazeneca.com/media-centre/press-releases/2021/evusheld-long-acting-antibody-combination-authorized-for-emergency-use-in-the-us-for-pre-exposure-prophylaxis-prevention-of-covid-19.html>

<http://publichealth.lacounty.gov/eprp/lahan/alerts/LAHAN%20EvusheldNewEUA022522.pdf>



Translate

A-Z Index

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z ALL

Font Size | **A A A**



Acute Communicable Disease Control

Vaccine ▾

Testing ▾

Reporting

Health Facilities ▾

Isolation/Quarantine ▾

LAHAN Alerts



COVID-19

Monoclonal & Antiviral Therapy for Non-Hospitalized Patients

Healthcare Provider Hub

Vaccine ▾

Therapeutics ▾

Isolation/Quarantine ▾

Testing ▾

Reporting

Health Facilities ▾

PPE & Infection Prevention ▾

Multisystem Inflammatory Syndrome

This webpage is specifically intended for the medical community.



Click [here](#) to visit DPH's COVID-19 Medications webpage for the general public.

Introduction

See the NIH [COVID-19 Treatment Guidelines](#) for comprehensive information and the CDC Health Advisory (12-31-21): [Using Therapeutics to Prevent and Treat COVID-19](#)

Contents

Who should receive outpatient therapy?

How to prioritize patients for treatment if not enough medication is available for all ill persons

Currently available treatments



Resources

- DHCS COVID-19 Uninsured Group Program Website:
 - <https://www.dhcs.ca.gov/services/medi-cal/eligibility/Pages/COVID-19-Presumptive-Eligibility-Program.aspx>
- LAC DPH Laboratory Reference Guide:
 - <http://publichealth.lacounty.gov/acd/docs/COVIDLabReferenceGuide.pdf>
- California Testing Taskforce Laboratory List:
 - <https://testing.covid19.ca.gov/covid-19-testing-task-force-laboratory-list/>
- LAC DPH Guidelines for Antigen Testing in SNFs:
 - <http://publichealth.lacounty.gov/acd/ncorona2019/healthfacilities/snf/antigen/>
- Test Reporting Protocol:
 - <http://publichealth.lacounty.gov/acd/docs/SNFReportingProtocolDiagram.pdf>
- LAC DPH Post-Surge Dashboard:
 - <http://publichealth.lacounty.gov/media/coronavirus/data/post-surge-dashboard.htm>
- CDC COVID-19 Data Tracker for Community Transmission:
 - https://covid.cdc.gov/COVID-data-tracker/#county-view?list_select_state=all_states&list_select_county=all_counties&data-type=Risk
- LAC DPH Therapeutics Webpage:
 - <http://publichealth.lacounty.gov/acd/ncorona2019/Therapeutics/>
- National Institutes of Health COVID-19 Treatment Guidelines:
 - <https://www.covid19treatmentguidelines.nih.gov/>