

COVID-19 Outpatient Therapeutics

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CDPH



Main Points

- **Effective treatment** for outpatients with mild to moderate COVID-19 **is available** and **should be offered to all high-risk patients** if they meet criteria for treatment based on EUAs
- We are **not in a state of scarcity**, all patients at high risk for disease progression with a COVID-19 positive test (PCR or antigen) who are within the treatment window should be offered treatment
- Providers should **review** product **EUAs** as well as the **NIH Treatment Guidelines** prior to using outpatient therapeutics
- **Clinical guidance is available** to assist in the selection of an appropriate COVID-19 therapeutic as well the navigation of some of the clinical complexities of using these drugs (i.e. Paxlovid drug interactions)

Available Outpatient Therapies at Each Disease Stage

Treatment Options	SARS-CoV-2 Negative (-)		SARS-CoV-2 Positive (+)
	Not Exposed	Exposed	Mild to Moderate Illness in Individual at High Risk for Disease Progression
	Pre-Exposure Prophylaxis (PrEP)	Post-Exposure Prophylaxis (PEP)	Treatment
	Long-Acting Monoclonal Antibody <ul style="list-style-type: none"> Tixagevimab/cilgavimab (Evusheld) 	Currently no authorized treatments*	Monoclonal Antibodies* <ul style="list-style-type: none"> — Sotrovimab** Bebtelovimab Antivirals <ul style="list-style-type: none"> Nirmatrelvir/ritonavir (Paxlovid) Remdesivir (Veklury) Molnupiravir (Lagevrio)

*The anti-SARS-CoV-2 monoclonal antibodies bamlanivimab/etesevimab and casirivimab/imdevimab (REGEN COV) were previously FDA authorized for PEP and treatment, but these are not effective against the Omicron variant and are currently **not authorized** for use in any US state per the FDA. This may change in the future depending on the prevailing variant.

**Sotrovimab has reduced effectiveness against BA.2; distribution of Sotrovimab was paused to California on 3/29/2022

Treatment of Acutely Ill Outpatients

Available Anti-SARS-COV-2 Treatments: Antivirals

Drug	Route	Age groups authorized for treatment	Timing of Treatment	Effectiveness	Activity Against Variants Currently Circulating	Clinical considerations
Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid) Orally twice daily for 5 days	Oral	12 years and older and weighing at least 40 kg	As soon as possible, but within 5 days of symptom onset	Compared to placebo, a <u>relative risk reduction of 89%</u> in hospitalizations or deaths.	Effective against Delta and Omicron	Drug interactions; Caution if concern for undiagnosed HIV; Renally dosed; Caution if severe hepatic impairment
Remdesivir (Veklury) 200 mg IV on Day 1, followed by 100 mg IV daily on Days 2 and 3	Intravenous	FDA approved in 12 years and older and weighing at least 40 kg; EUA for <12 years of age weighing 3.5 to 40 kg Only product currently available to all age groups	As soon as possible, but within 7 days of symptom onset	Compared to placebo, a <u>relative risk reduction of 87%</u> in hospitalizations or deaths.	Effective against Delta and Omicron	Caution in renal or hepatic impairment
Molnupiravir (Legevrion) 800 mg Orally twice daily for 5 days	Oral	18 years and older	As soon as possible, but within 5 days of symptom onset	Compared to placebo, a <u>relative risk reduction of 30%</u> in hospitalizations or deaths.	Effective against Delta and Omicron	Caution in individuals of reproductive age; require use of reliable method of contraception

Available Anti-SARS-COV-2 Treatments: Monoclonal Antibodies

Drug	Route	Age groups authorized for treatment	Timing of Treatment	Treatment Effectiveness	Activity Against Variants Currently Circulating	Clinical considerations
Bebtelovimab 175 mg Given as a single intravenous injection over at least 30 seconds	Intravenous	12 years and older and weighing at least 40 kg	As soon as possible, but within 7 days of symptom onset	Only phase 1/2 data; no risk reduction data	Effective against Delta and Omicron	Caution if any history of hypersensitivity

What is Mild to Moderate Illness?

Mild Illness	Moderate Illness
<p>Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.</p>	<p>Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation (SpO₂) $\geq 94\%$ on room air at sea level.</p>

Who is High Risk?

- CDC list of conditions:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>
- Age is the strongest risk factor for severe COVID-19 outcomes, people aged 65 years or older accounted for 81% of U.S. COVID-19 related deaths in 2020

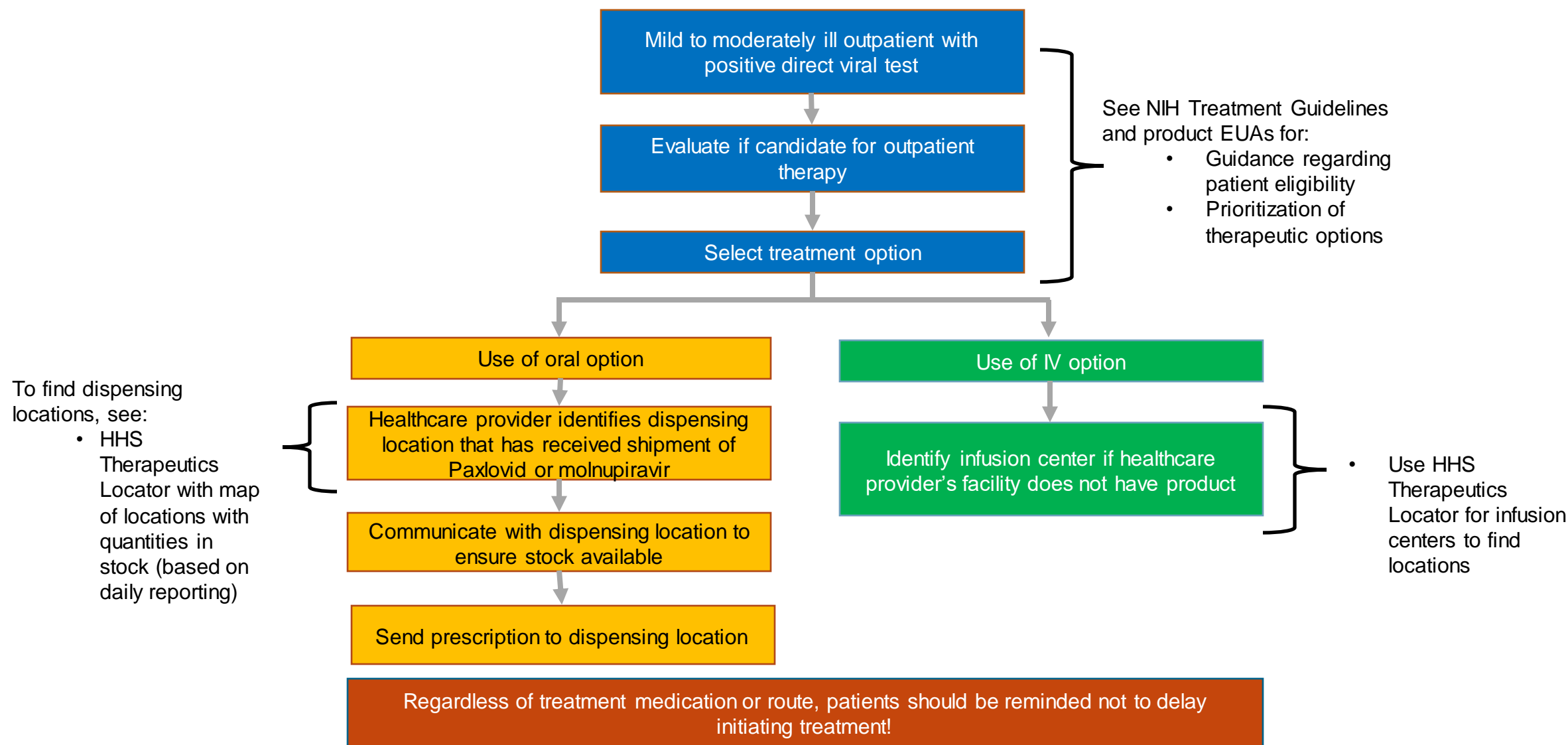
Text of EUAs

Conditions:

- Older age (for example age ≥ 65 years of age)
- <1 year old
- Obesity or being overweight
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or treatment
- Cardiovascular disease or hypertension
- Chronic lung disease
- Sickle cell disease
- Neurodevelopmental disorders
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation)

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization under the EUA is not limited to the medical conditions or factors listed above

Prescribing Treatment for Mild to Moderate Disease



NIH Prioritization of Treatment Options

In order of preference, the NIH recommends using one of the following treatment options (taking into account a patient's full clinical status, including drug-drug interactions) for mild to moderate infection:

1. **Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid)** orally twice daily for 5 days, initiated as soon as possible and within 5 days of symptom onset in those aged ≥ 12 years and weighing ≥ 40 kg
2. ~~**Sotrovimab 500 mg*** as a single IV infusion, administered as soon as possible and within 10 days of symptom onset in those aged ≥ 12 years and weighing ≥ 40 kg~~
3. **Remdesivir 200 mg IV** on Day 1, followed by **remdesivir 100 mg IV** daily on Days 2 and 3, initiated as soon as possible and within 7 days of symptom onset in those aged ≥ 12 years and weighing ≥ 40 kg; EUA in children under the age of 12 years. Doses should be adjusted for pediatric patients.
4. **Bebtelovimab 175 mg** as a single IV injection **OR Molnupiravir 800 mg** orally twice daily for 5 days, initiated as soon as possible and within 5 days of symptom onset in those aged ≥ 18 years

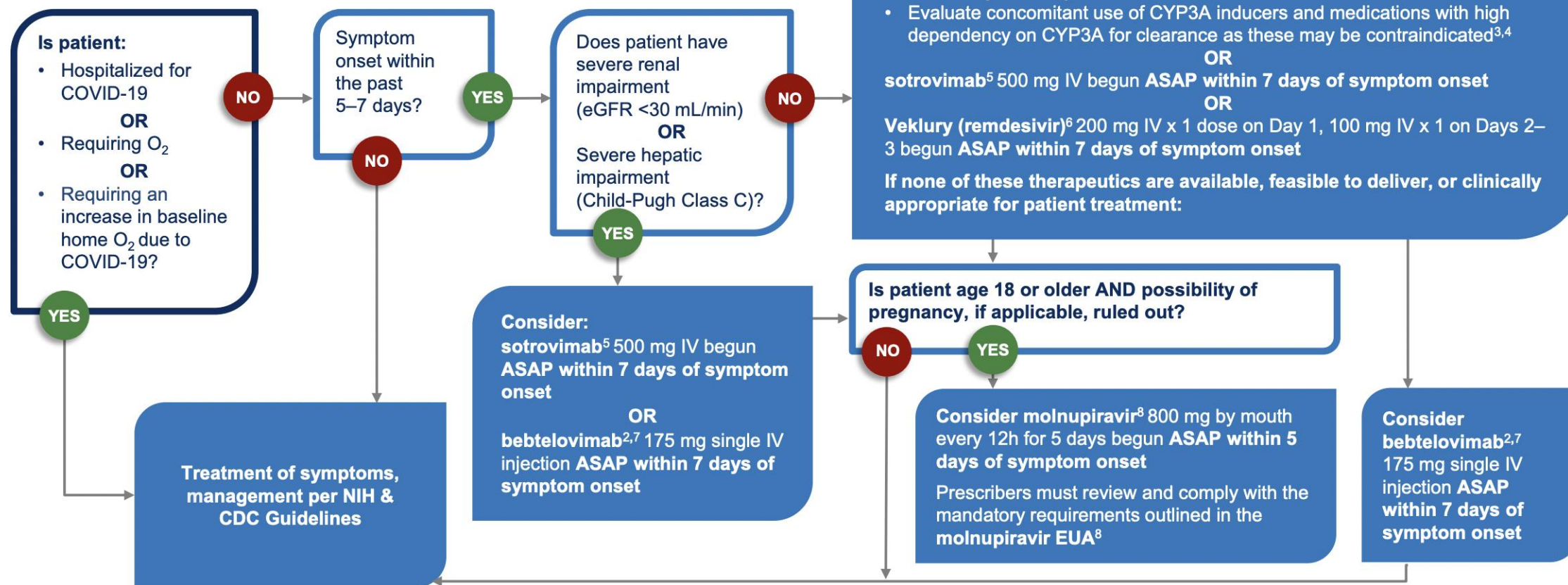
Use bebtelovimab or molnupiravir **ONLY** when none of the above options can be used

**Sotrovimab has reduced effectiveness against BA.2; use of product in California has been paused by HHS*

Clinical Decision Making

COVID-19 Outpatient Therapeutics Clinical Decision Aid for Ages 12+

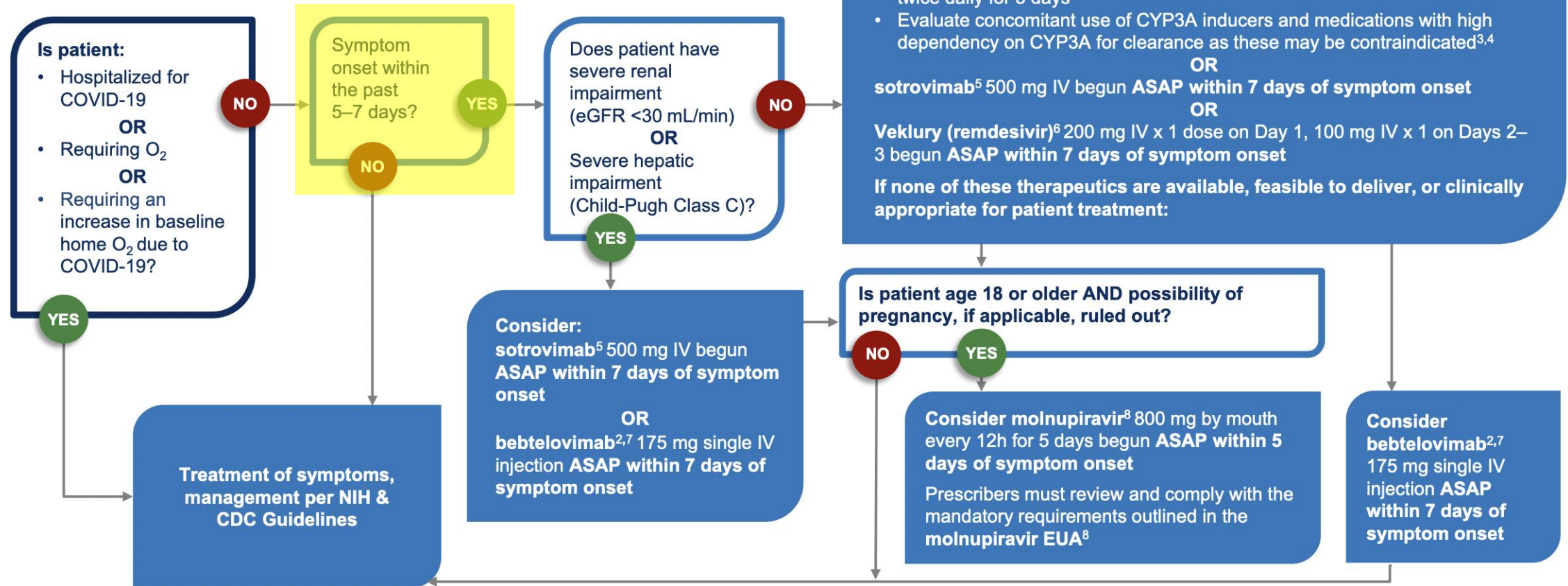
Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease



Clinical Decision Making

COVID-19 Outpatient Therapeutics Clinical Decision Aid for Ages 12+

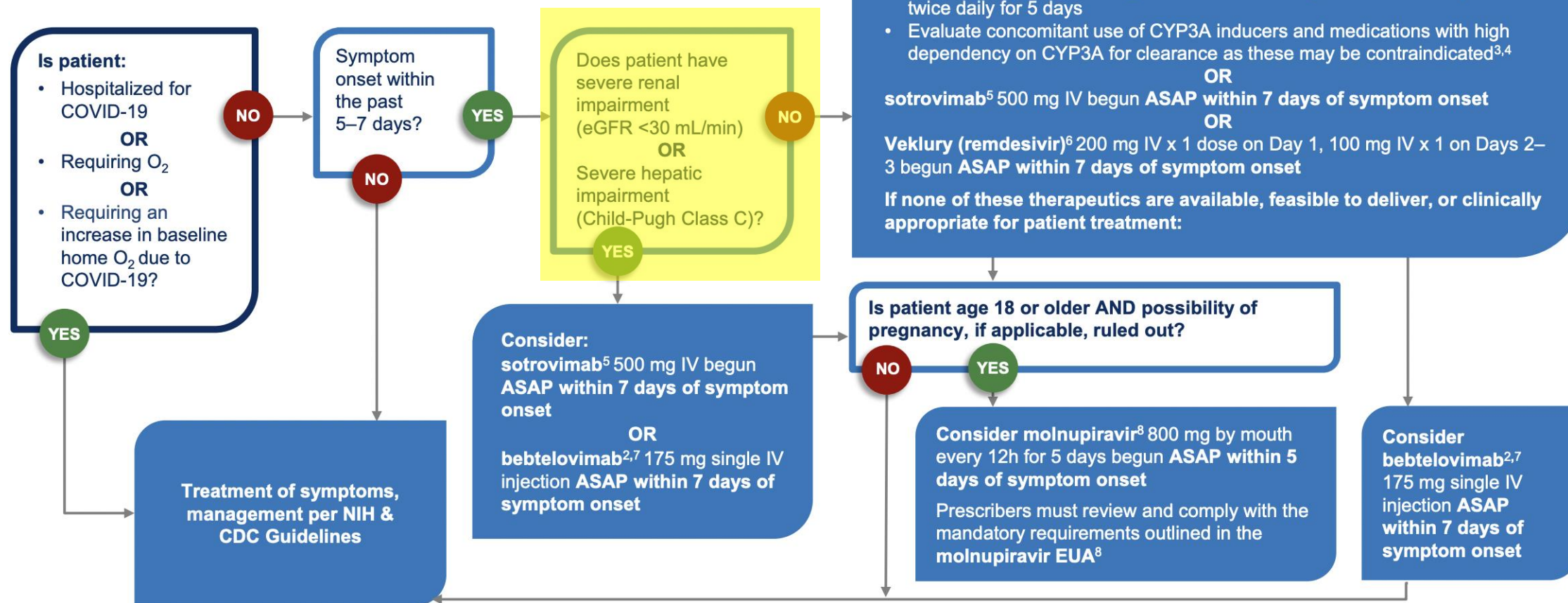
Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease



Clinical Decision Making

COVID-19 Outpatient Therapeutics Clinical Decision Aid for Ages 12+

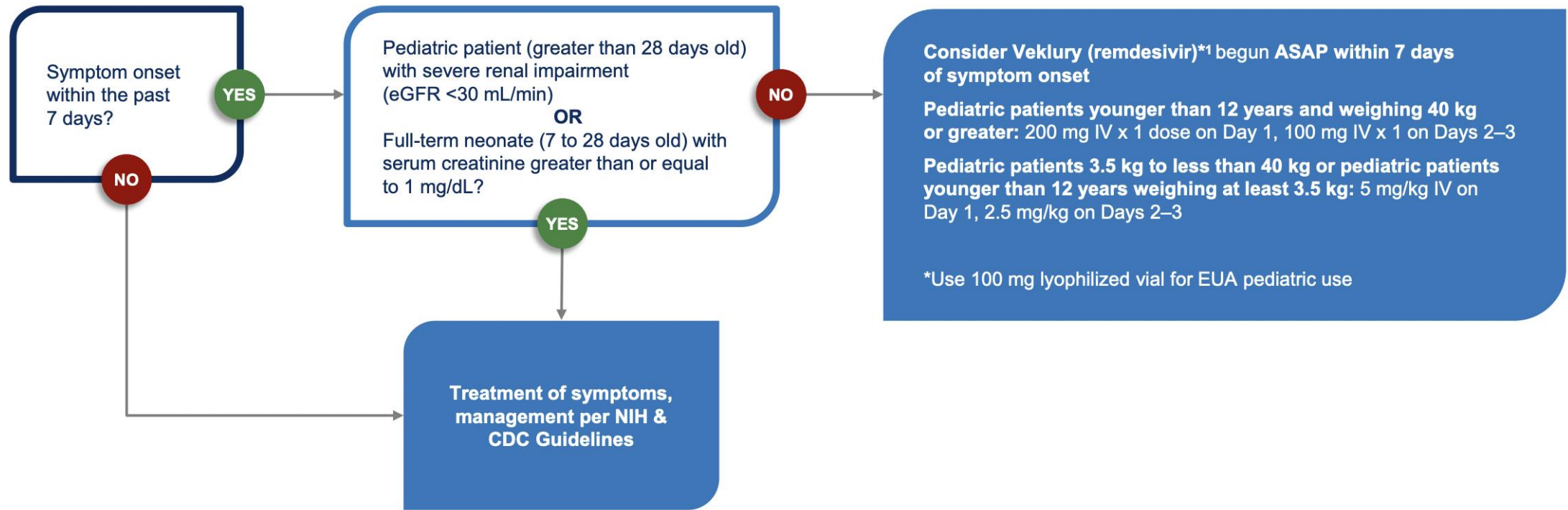
Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease



Clinical Decision Making

Clinical Decision Aid for Pediatric Patients

Outpatient **3.5 kg to less than 40 kg** or **younger than 12 years of age**
weighing at least 3.5 kg, with mild to moderate COVID-19 and at high risk
for progression to severe disease



Drug Interactions With Paxlovid

- Paxlovid has significant and complex drug-drug interactions, primarily due to the ritonavir component of the combination
- Ritonavir is a strong Cytochrome P450 3A4 (CYP3A4) inhibitor
- CYP3A4 oxidizes small foreign organic molecules such as drugs so that they can be removed from the body
- Additionally, ritonavir is an inhibitor, inducer, and substrate of various other drug-metabolizing enzymes and/or drug transporters.
- CYP3A4 inhibition occurs rapidly after initiating ritonavir, with maximum inhibition occurring within 48 hours
- After ritonavir is discontinued, 80% to 90% of CYP3A4 inhibition resolves within 3 days.

Drug Interactions With Paxlovid

- Drug interactions that can be safely managed should not preclude the use of Paxlovid
- Multiple resources are available to guide prescribers through potential interactions and suggest mitigating steps:
 - NIH Treatment Guidelines: <https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid/>
 - Liverpool COVID-19 Drug Interaction Tool: <https://covid19-druginteractions.org/checker>

Drug Interactions With Paxlovid

Prescribe an alternative COVID-19 therapy

Start Paxlovid and temporarily hold or adjust the dosing of medication(s) that might be problematic

Prescribe an Alternative COVID-19 Therapy For cases where drug-drug interaction management strategies are not possible or feasible, or the potential risks of such strategies outweigh the potential benefits.	Temporarily Withhold Concomitant Medication, If Clinically Appropriate For guidance on restarting the concomitant medication, consult the Liverpool COVID-19 Drug Interactions website . ^b If withholding is not clinically appropriate, use an alternative concomitant medication or COVID-19 therapy.	Adjust Concomitant Medication Dose and Monitor for Adverse Effects Consult the Liverpool COVID-19 Drug Interactions website . ^b for guidance. If the dose of the concomitant medication cannot be adjusted, withhold the medication (if clinically appropriate) or use an alternative concomitant medication or COVID-19 therapy.
<ul style="list-style-type: none"> Amiodarone Apalutamide Bosentan Carbamazepine Clopidogrel^a Clozapine Disopyramide Dofetilide Dronedarone Enzalutamide Eplerenone Ergot derivatives Flecainide Glecaprevir/pibrentasvir Ivabradine Lumacaftor/ivacaftor Lumateperone Lurasidone Meperidine (pethidine) Midazolam (oral) Phenobarbital Phenytoin Pimozide Primidone Propafenone Quinidine Rifampin Rifapentine Sildenafil for PH St. John's wort Tadalafil for PH Tolvaptan Vardenafil for PH Voclosporin 	<ul style="list-style-type: none"> Alfuzosin Aliskiren Atorvastatin Avanafil Chemotherapy^c Clonazepam^d Clorazepate^d Colchicine^e Diazepam^d Eletriptan Erythromycin Estazolam^d Everolimus^f Finerenone Flibanserin Flurazepam^d Lomitapide Lovastatin Naloxegol Ranolazine Rimegepant Rivaroxaban^g Rosuvastatin Salmeterol Silodosin Simvastatin Sirolimus^f Suvorexant Tacrolimus^f Ticagrelor Triazolam^d Ubrogepant Vorapaxar 	<ul style="list-style-type: none"> Alprazolam^d Amlodipine Apixaban Aripiprazole Brexpiprazole Buspirone Cariprazine Chlordiazepoxide^d Cilostazol Clarithromycin Clobazam^d Cyclosporine^f Darifenacin Digoxin Elexacaftor/tezacaftor/ivacaftor Eluxadoline Fentanyl Iloperidone Itraconazole Ivacaftor Ketoconazole Maraviroc Mexiletine Oxycodone Pimavanserin Quetiapine Rifabutin Riociguat Saxagliptin Sildenafil for ED Ruxolitinib Tadalafil for ED Tamsulosin Tezacaftor/ivacaftor Trazodone Vardenafil for ED

For full details, see the Liverpool COVID-19 Drug Interaction Tool: <https://covid19-druginteractions.org/checker>

Considerations for HIV Patients with COVID-19

- Triage, management, and treatment of COVID-19 in people with HIV are generally the same as those for the general population
- People with HIV who are taking ritonavir-based or cobicistat-based antiretroviral therapy (ART) can receive ritonavir-boosted nirmatrelvir (Paxlovid) to treat COVID-19 without altering or interrupting their ART

Molnupiravir Considerations

- Because of bone and cartilage toxicity, NOT authorized for use in individuals <18 years of age
- Causes fetal harm, do not use in pregnant individuals
- Breast feeding is not recommended during treatment with molnupiravir and for 4 days after the last dose
- Individuals of childbearing potential must use effective contraception:
 - Females: use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose
 - Males: Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose

HHS Treatment Locator

Therapeutic Distribution Locator for Provider Use

State, Territory, or Jurisdiction
All

Therapeutic Selector
All

Locations

911

ADVENTIST HEALTH CLEARLAKE
15630 18TH AVE - HWY
53, CLEARLAKE, CA 95422
Sotrovimab, Product #00173-0901-86
38 Available

ADVENTIST HEALTH HANFORD
115 MALL DRIVE, HANFORD, CA 93230
Sotrovimab, Product #00173-0901-86
115 Available

ADVENTIST HEALTH HANFORD
115 Mall Drive, Hanford, CA 93230
Paxlovid, Product #00069-1085-30
118 Available

ADVENTIST HEALTH HANFORD
115 Mall Drive, Hanford, CA 93230
Molnupiravir, Product #00006-5055-06
203 Available

ADVENTIST HEALTH HANFORD
115 Mall Drive, Hanford, CA 93230
Bebtelovimab, Product #00002-7589-01
119 Available

ADVENTIST HEALTH LODI MEMORIAL
975 S FAIRMONT AVENUE, LODI, CA 95240
Sotrovimab, Product #00173-0901-86
44 Available

ADVENTIST HEALTH REEDLEY
372 W CYPRESS AVE, REEDLEY, CA 93654
Sotrovimab, Product #00173-0901-86
36 Available

Use search glass below to find locations near an address.

Evusheld
Available: 11,008

Molnupiravir
Available: 36,625

Paxlovid
Available: 11,317

Bebtelovimab
Available: 1,632

Sotrovimab
Available: 6,461

California State Parks, Esri, HERE, Garmin, FAO, NOAA, USGS, Bureau of Land Management, EPA, NPS | CDC, HHS

Powered by Esri

Vaccinate
ALL 58

<https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/>

Test to Treat Sites

Need help finding a place to get medication? Call [1-800-232-0233](tel:1-800-232-0233) (TTY [888-720-7489](tel:888-720-7489))

Get medication for COVID-19

COVID-19 medications are now available through your doctor, local pharmacies, and health clinics.
If you have COVID-19 symptoms, do not wait to get treated.
You must take oral COVID-19 medication within 5 days of your first COVID-19 symptoms.
Use the tool below to find a location that is right for you.

Find COVID-19 Medication

Alameda County, CA, USA

0 10 mi 250

Results: 40

Locations with testing, medical visits, and medication (Test-to-Treat)

CVS Store #09251

3999 Santa Rita Road, Pleasanton, CA 94588
[Book an appointment at CVS Store #09251](#)

(3.53 mi)

> Locations to fill a prescription



Clear search location

How to get medication

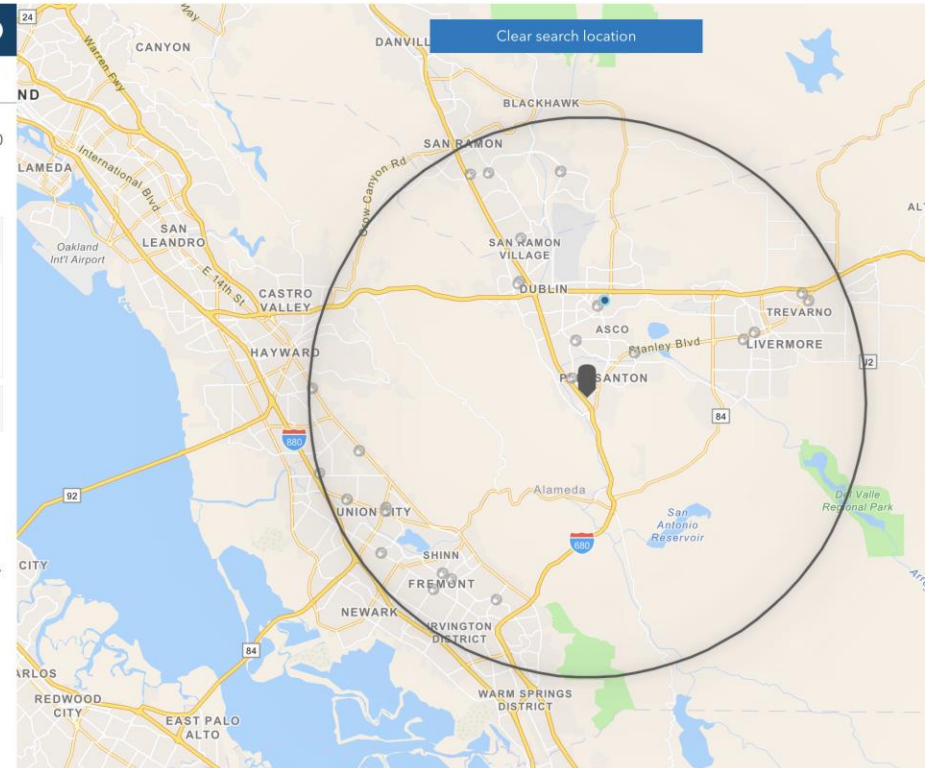
1. Locations to get testing, medical visits, and medication (Test-to-Treat)

Some pharmacy clinics and health centers can prescribe and give you medication at the same location.

[Learn more about the Test-to-Treat program.](#)

2. Locations to fill a prescription

Any healthcare provider can evaluate and prescribe you COVID-19 medication just as they normally would. You can fill those prescriptions at any location in this tool.



California State Parks, Esri, HERE, Garmin, SafeGraph, METI/NASA, USGS, Bureau of Land Management, EPA, NPS, USDA | HHS

Data available for download at [HealthData.gov](https://healthdata.gov)

Prophylaxis for COVID-19

Post-Exposure Prophylaxis

- Currently we have no FDA authorized or approved therapeutics for post-exposure prophylaxis
- Bam/Ete and REGEN COV are the only drugs with EUAs for post-exposure prophylaxis and neither are effective against Omicron
- As of January 24, 2022:
 - The FDA has revised bam/ete and REGEN COV EUAs to limit use to patients who are likely to have been exposed or infected to a variant that is susceptible to these treatments
 - Use of bam/ete and REGEN COV are **not authorized** for use in any US state

Pre-Exposure Prophylaxis: Evusheld

Drug	Route	Age groups authorized for treatment	Pre-Exposure Prophylaxis Effectiveness	Activity Against Variants Currently Circulating	Clinical Considerations
Tixagevimab 300 mg / cilgavimab 300 mg (Evusheld) Given as two separate consecutive injections Redose every 6 months	Intramuscular	12 years and older and weighing at least 40 kg	Reduced the risk of developing symptomatic COVID-19 by <u>77% compared to placebo</u> .	Effective against Delta and Omicron	Use with caution if history of hypersensitivity In clinical trial, rare, serious cardiac adverse events occurred in 0.6% of participants in the Evusheld arm and in 0.2% of participants in the placebo arm

Pre-Exposure Prophylaxis: Evusheld

- Use of Evusheld as a pre-exposure prophylaxis (PrEP) is authorized for adults and adolescents (aged ≥ 12 years and weighing ≥ 40 kg) who do not have SARS-CoV-2 infection, who have not been recently exposed to an individual with SARS-CoV-2 infection, **AND** who:
 - Are moderately to severely immunocompromised and may have inadequate immune response to COVID-19 vaccination; **or**
 - Are not able to be fully vaccinated with any available COVID-19 vaccines due to a history of severe adverse reaction to a COVID-19 vaccine or any of its components.

Evusheld is not a substitute for COVID-19 vaccination and should not be used in unvaccinated individuals for whom COVID-19 vaccination is recommended and who are anticipated to have an adequate response.

Therapeutic Allocation and Supply

Current Supply of COVID-19 Outpatient Therapeutics

- Supply of therapeutic products in California is currently **not** limited; we are currently **not** in a state of scarcity
- At this time, **all patients** who are eligible for treatment with COVID-19 treatments should be offered treatment
- Should product ever be scarce in the future, the NIH Treatment Guidelines provide direction on patient prioritization:
<https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/>

Clinical Cases

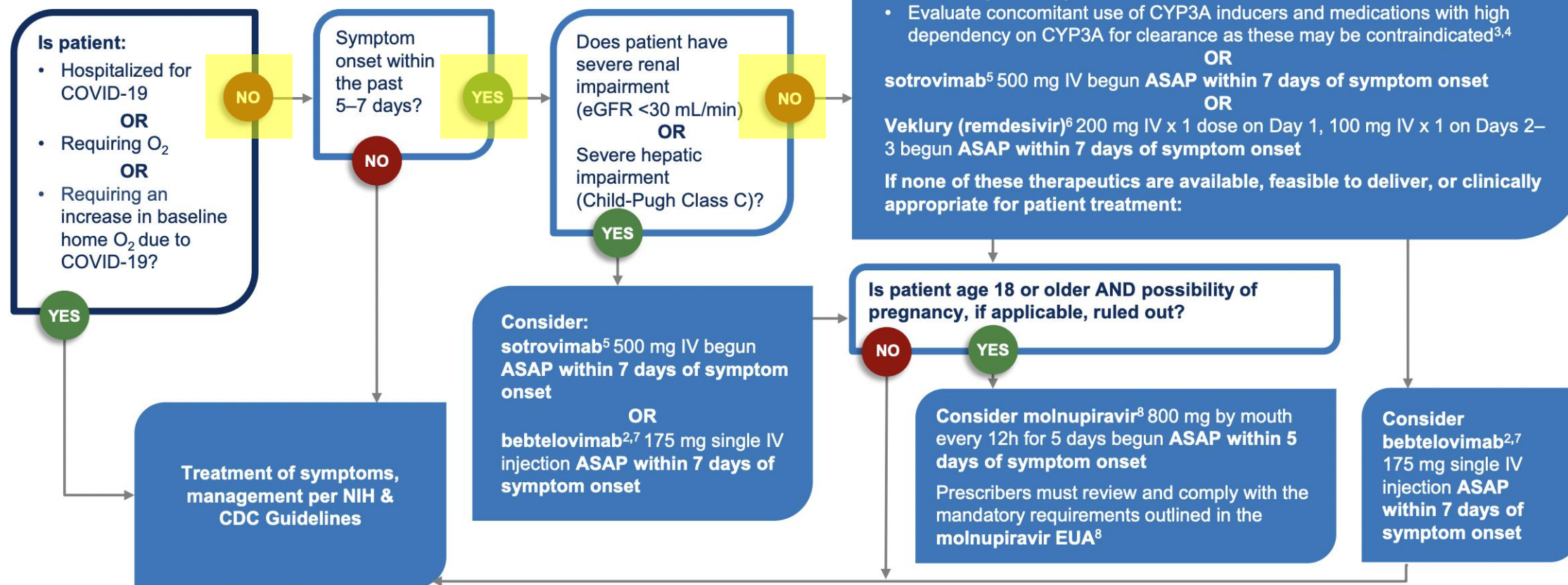
Clinical Cases #1: The Straightforward Patient

66 yo obese male on no medications with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test. No history of renal or hepatic impairment.

Clinical Decision Making

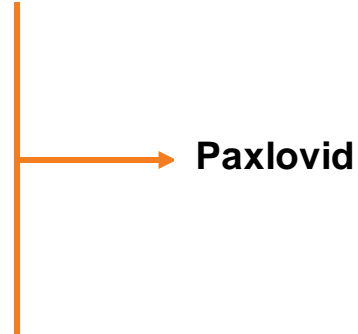
COVID-19 Outpatient Therapeutics Clinical Decision Aid for Ages 12+

Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease



Clinical Case #1: The Straightforward Patient

66 yo obese male on no medications with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test. No history of renal or hepatic impairment.



Clinical Case #2: Patient on Multiple Medications

50 yo male with history of diabetes, high blood pressure, obesity, and high cholesterol presenting with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test. No history of renal or hepatic impairment.

Medications:

Metformin

Simvastatin

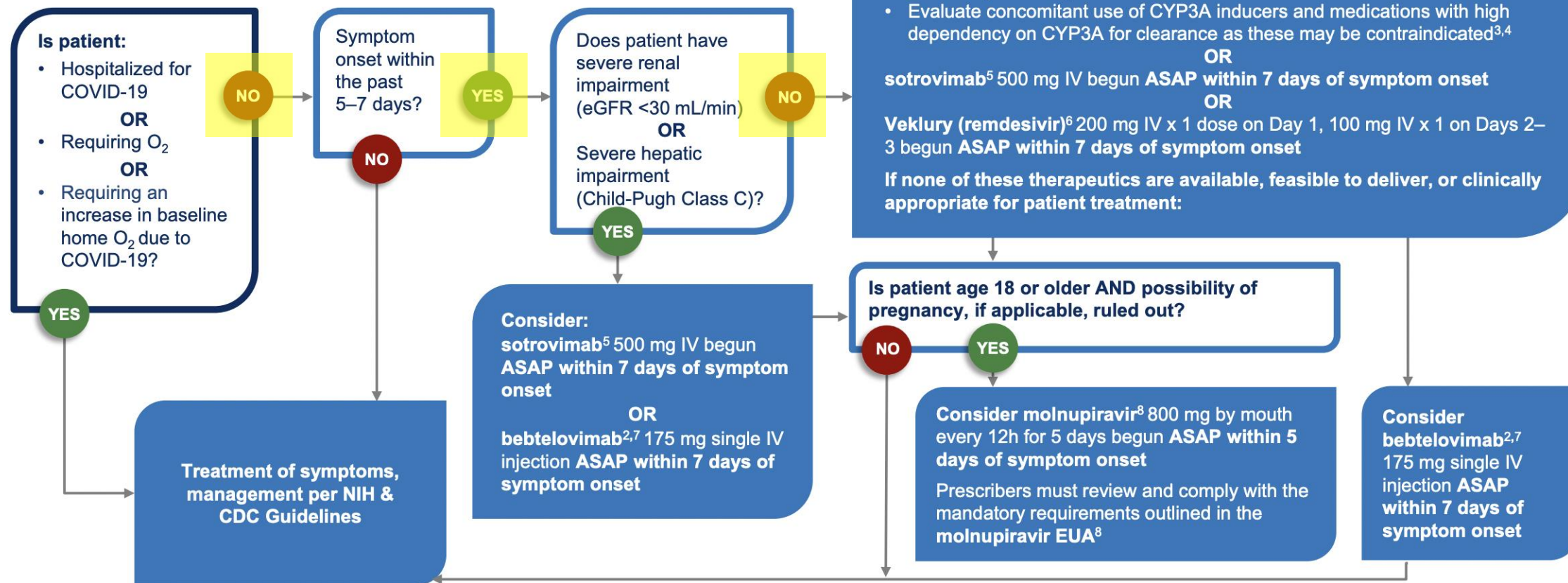
Amlodipine

Clinical Case #2: Patient on Multiple Medications

COVID-19 Outpatient Therapeutics

Clinical Decision Aid for Ages 12+

Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease



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50 yo male with history of diabetes, high blood pressure, obesity, and high cholesterol presenting with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test. No history of renal or hepatic impairment.

Medications:

Metformin

Simvastatin

Amlodipine




Paxlovid


Remdesivir

Bebtelovimab

Molnupiravir

Clinical Case #2: Patient on Multiple Medications

 COVID-19 Drug Interactions

 UNIVERSITY OF LIVERPOOL

[About](#) [Interaction Checkers](#) [Prescribing Resources](#) [Contact Us](#)

ions with selected WHO Essential Medicines and Paxlovid (nirmatrelvir/ritonavir) now available in the Prescribing Resources section - [click here for the PDF](#).

If a drug is not listed below it cannot automatically be assumed it is safe to coadminister.

COVID Drugs	Co-medications	Drug Interactions
<input checked="" type="checkbox"/> paxlo <input type="text"/>	<input checked="" type="checkbox"/> metform <input type="text"/>	<input checked="" type="checkbox"/> Check COVID/COVID drug interactions Reset Checker
<input checked="" type="radio"/> A-Z <input type="radio"/> Class <input type="radio"/> Trade	<input checked="" type="radio"/> A-Z <input type="radio"/> Class	Switch to table view Results Key
<input checked="" type="checkbox"/> Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.) <input type="text"/>	<input checked="" type="checkbox"/> Simvastatin <input type="text"/>	Do Not Coadminister
	<input checked="" type="checkbox"/> Amlodipine <input type="text"/>	Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.)
	<input checked="" type="checkbox"/> Metformin <input type="text"/>	Simvastatin
<input checked="" type="checkbox"/> Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.) <input type="text"/>	<input checked="" type="checkbox"/> Metformin <input type="text"/>	More Info <input type="text"/>
		Potential Interaction
		Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.)
		Amlodipine
		More Info <input type="text"/>
		No Interaction Expected
		Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.)

Clinical Case #2: Patient on Multiple Medications

Drugs that should not be coadministered (RED)

Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.) + Simvastatin

Coadministration of simvastatin and potent CYP3A4 inhibitors, such as ritonavir, is contraindicated due to the high risk of presenting serious reactions such as risk of myopathy including rhabdomyolysis. It is highly advised to stop simvastatin during nirmatrelvir/ritonavir treatment. The pragmatic approach to stop temporarily simvastatin (or any other statins) is acceptable considering that it will not negatively affect the therapeutic effect but can minimize the risk for adverse events related to a drug interaction. Given the mechanism-based inhibition of nirmatrelvir/ritonavir, simvastatin treatment will have to be resumed 3 days after the last dose of nirmatrelvir/ritonavir.



Hold simvastatin, resume 3 days after last dose of Paxlovid

Potential clinically significant interaction - likely to require additional monitoring, alteration of drug dosage or timing of administration (AMBER)

Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.) + Amlodipine

Coadministration has not been studied. Amlodipine is metabolized by CYP3A4. Nirmatrelvir/ritonavir is predicted to increase amlodipine exposure by ~2-fold based on drug-drug interactions studies with amlodipine and indinavir/ritonavir or paritaprevir/ritonavir leading to the recommendation to reduce amlodipine dosage by 50%. However, a dose adjustment can be optional in the case of amlodipine given that patients can be advised to monitor for symptoms of hypotension and to temporarily pause the antihypertensive drug if needed. The inhibitory effect of ritonavir is expected to last up to 3 days after the last administered dose of nirmatrelvir/ritonavir.



Reduce amlodipine dose by 50% OR monitor blood pressure and stop drug if low

No clinically significant interaction expected (GREEN)

Nirmatrelvir/ritonavir (Please read the interaction details as management of these interactions may be complex.) + Metformin



No change to metformin dosing

Clinical Case #2: Patient on Multiple Medications

50 yo male with history of diabetes, high blood pressure, obesity, and high cholesterol presenting with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test. No history of renal or hepatic impairment.

Medications:

Metformin

Simvastatin

Amlodipine

Paxlovid	Drug interactions, but all manageable
Remdesivir	Infusion center required, three days of treatment
Bebtelovimab	Infusion center required; less clinical data
Molnupiravir	Oral, but least effective medication

Clinical Case #3: Patient With Longer Symptom Duration

50 yo male with history of diabetes, high blood pressure, obesity, and high cholesterol presenting with **6 days** of fever and cough; positive SARS-CoV-2 on home antigen test. No history of renal or hepatic impairment.

Medications:

Metformin

Simvastatin

Amlodipine

Clinical Case #3: Patient With Longer Symptom Duration

50 yo male with history of diabetes, high blood pressure, obesity, and high cholesterol presenting with **6 days** of fever and cough; positive SARS-CoV-2 on home antigen test. No history of renal or hepatic impairment.

Medications:

Metformin

Simvastatin

Amlodipine



Remdesivir

Infusion center required, three days of treatment

Bebtelovimab

Infusion center required; less clinical data

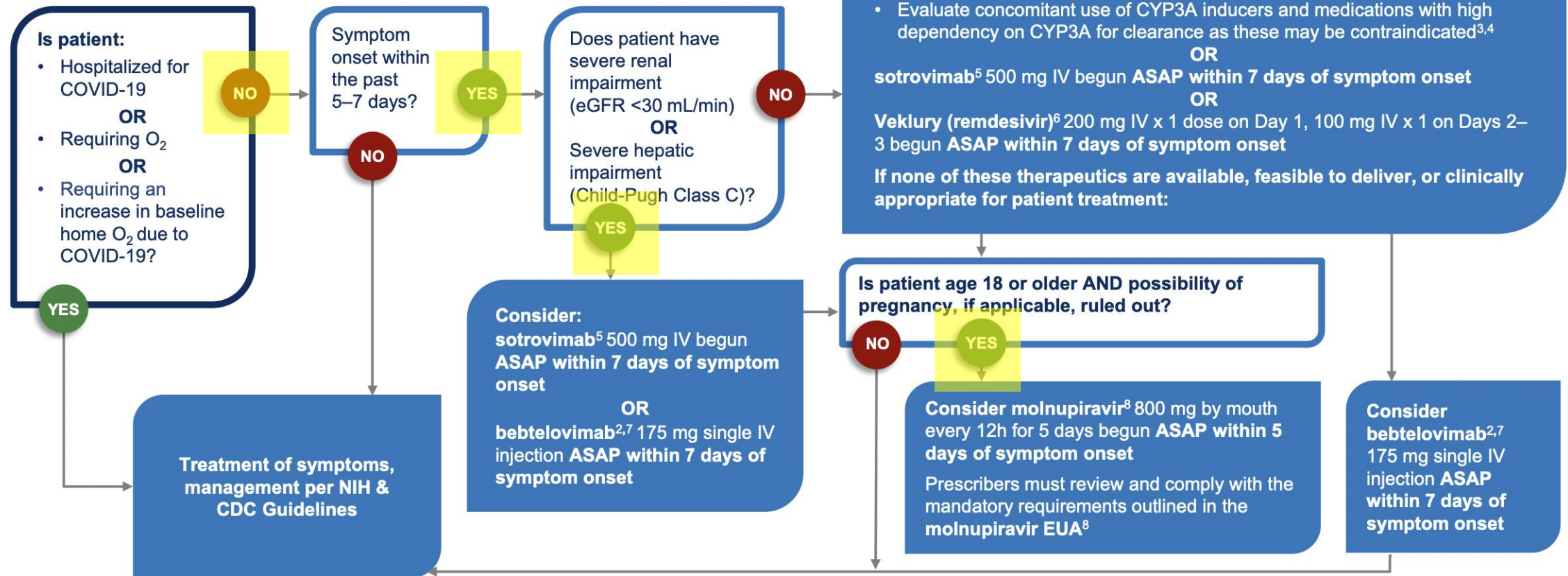
Clinical Case #4: Patient on Hemodialysis

50 yo male with history of diabetes, end stage renal disease and on hemodialysis M-W-Fri, high blood pressure, obesity, and high cholesterol presenting with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test.

Clinical Case #4: Patient on Hemodialysis

COVID-19 Outpatient Therapeutics Clinical Decision Aid for Ages 12+

Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease



Clinical Case #4: Patient on Hemodialysis

50 yo male with history of diabetes, end stage renal disease and on hemodialysis M-W-Fri, high blood pressure, obesity, and high cholesterol presenting with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test.



Bebtelovimab

Infusion center required; less clinical data

Molnupiravir

Oral, but likely least effective medication of the two options

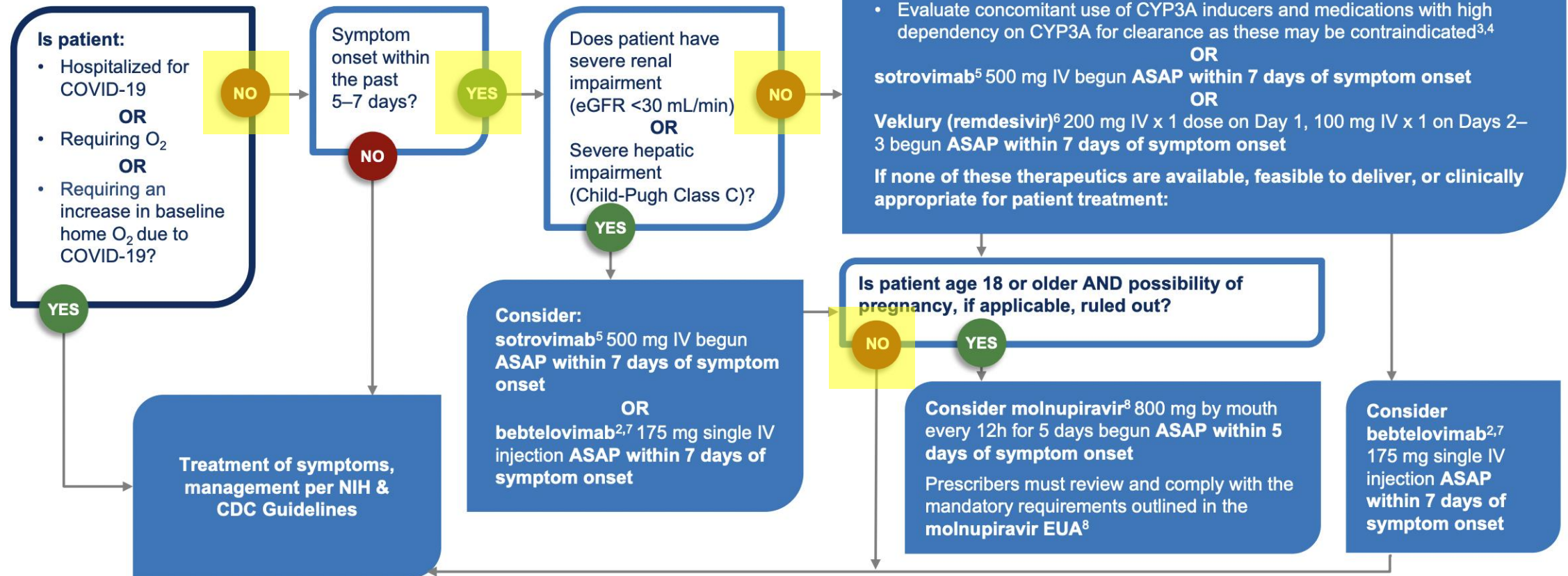
Clinical Case #5: Pregnant Patient

35 yo female who is 24 weeks pregnant with history of sickle cell disease with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test. No history of liver or kidney problems.

Clinical Case #5: Pregnant Patient

COVID-19 Outpatient Therapeutics Clinical Decision Aid for Ages 12+

Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease



Clinical Case #5: Pregnant Patient

35 yo female who is 24 weeks pregnant with history of sickle cell disease with 3 days of fever and cough; positive SARS-CoV-2 on home antigen test. No history of liver or kidney problems.



Paxlovid
Remdesivir
Bebtelovimab

Infusion center required, three days of treatment

Infusion center required; less clinical data

Patients Should be Counseled Regarding:

- COVID-19 in pregnancy is associated with adverse maternal and fetal outcomes, including preeclampsia, eclampsia, preterm birth, premature rupture of membranes, venous thromboembolic disease, and fetal death.
- For all drugs, insufficient data to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes

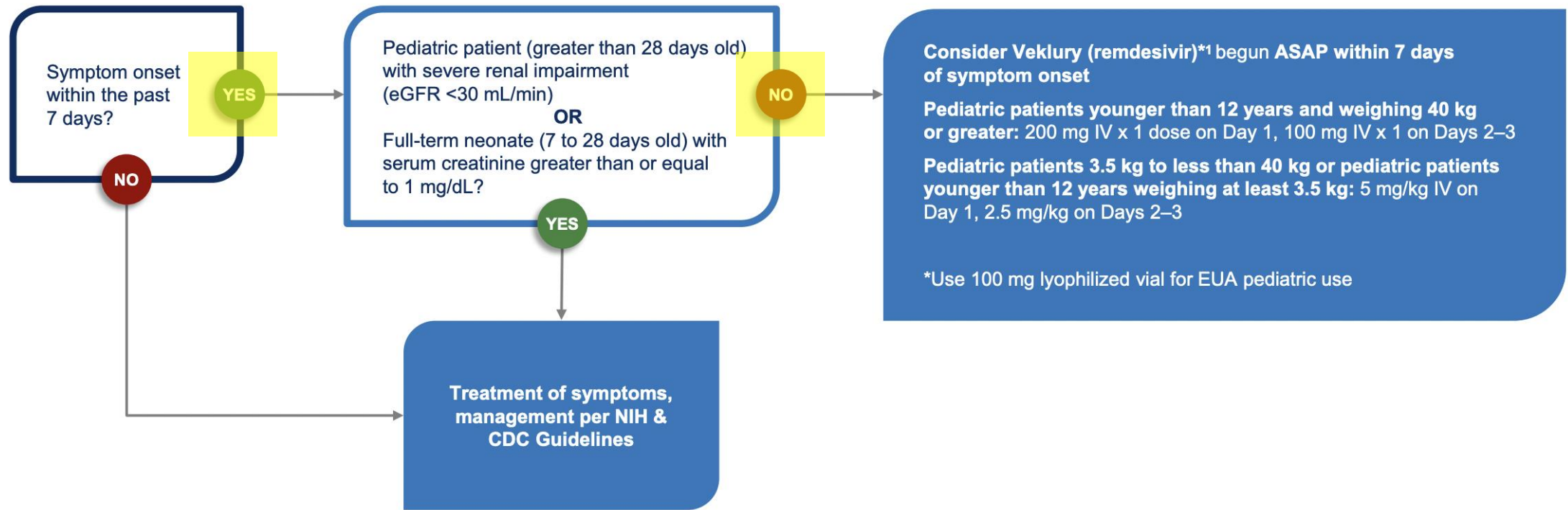
Clinical Case #6: Pediatric Case

8 yo female with cerebral palsy presenting with 3 days of fever and chills. Found to be SARS-CoV-2 PCR positive. No history of liver or kidney problems

Clinical Case #6: Pediatric Case

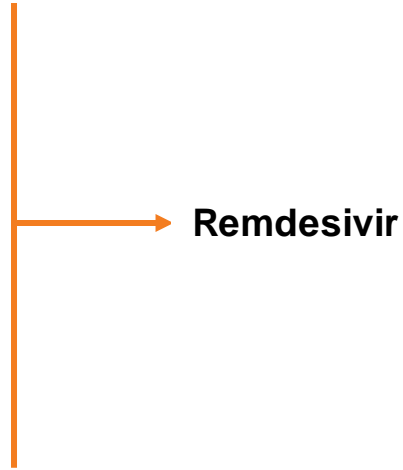
Clinical Decision Aid for Pediatric Patients

Outpatient **3.5 kg to less than 40 kg** or **younger than 12 years of age**
weighing at least 3.5 kg, with mild to moderate COVID-19 and at high risk
for progression to severe disease



Clinical Case #6: Pediatric Case

8 yo female with cerebral palsy presenting with 3 days of fever and chills. Found to be SARS-CoV-2 PCR positive. No history of liver or kidney problems



Infusion center required, three days of treatment; ONLY drug available in patients <12 years of age

Resources and Summary Points

Summary Points

- **Effective treatment** for outpatients with mild to moderate COVID-19 **is available** and **should be offered to all high-risk patients** if they meet criteria for treatment based on EUAs
- We are **not in a state of scarcity**, all patients at high risk for disease progression with a COVID-19 positive test (PCR or antigen) who are within the treatment window should be offered treatment
- Providers should **review** product **EUAs** as well as the **NIH Treatment Guidelines** prior to using outpatient therapeutics
- **Clinical guidance is available** to assist in the selection of an appropriate COVID-19 therapeutic as well the navigation of some of the clinical complexities of using these drugs (i.e. Paxlovid drug interactions)

Resources

- **Treatment**
 - NIH Guidance: <https://www.covid19treatmentguidelines.nih.gov>
 - COVID-19 Drug Interaction Tool: <https://covid19-druginteractions.org/checker>
 - CDPH Webpage: <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Treatments.aspx>
 - HHS: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/healthcare-professionals.aspx>
- **Locating Therapeutic Options**
 - HHS Therapeutic Locator: <https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/>
 - HHS Test to Treat: <https://covid-19-test-to-treat-locator-dhhs.hub.arcgis.com>
- **Information on Billing**
 - CMS Infusion Billing: <https://www.cms.gov/monoclonal>
 - Treatments Add-On Payment (NCTAP): <https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap>
- **Fact Sheets for Providers**
 - Paxlovid: <https://www.fda.gov/media/155050/download>
 - Remdesivir:
 - Use in ≥ 12 years of age: https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf
 - Use in <12 years of age: <https://www.fda.gov/media/137566/download>
 - Bebtelovimab: <https://www.fda.gov/media/156152/download>
 - Molnupiravir: <https://www.fda.gov/media/155054/download>
 - Evusheld: <https://www.fda.gov/media/154701/download>
- **Fact Sheets for Patients:**
 - Paxlovid: <https://www.fda.gov/media/155051/download>
 - Remdesivir: https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_patient_pi.pdf and for pediatric patients: <https://www.fda.gov/media/137565/download>
 - Bebtelovimab: <https://www.fda.gov/media/156153/download>
 - Molnupiravir: <https://www.fda.gov/media/155055/download>
 - Evusheld: <https://www.fda.gov/media/154702/download>