COVID-19 OUTPATIENT TREATMENT GUIDELINES ROADMAP

COVID-19 Real-Time Learning Network Brought to you by **CDC** and **SA**

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This resource is intended to serve as a guide on available outpatient COVID-19 treatment options, with links to FDA prescribing information, FDA Emergency Use Authorization, 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 Association¹⁵ and HHS.¹¹

Risk factors for severe COVID-1910

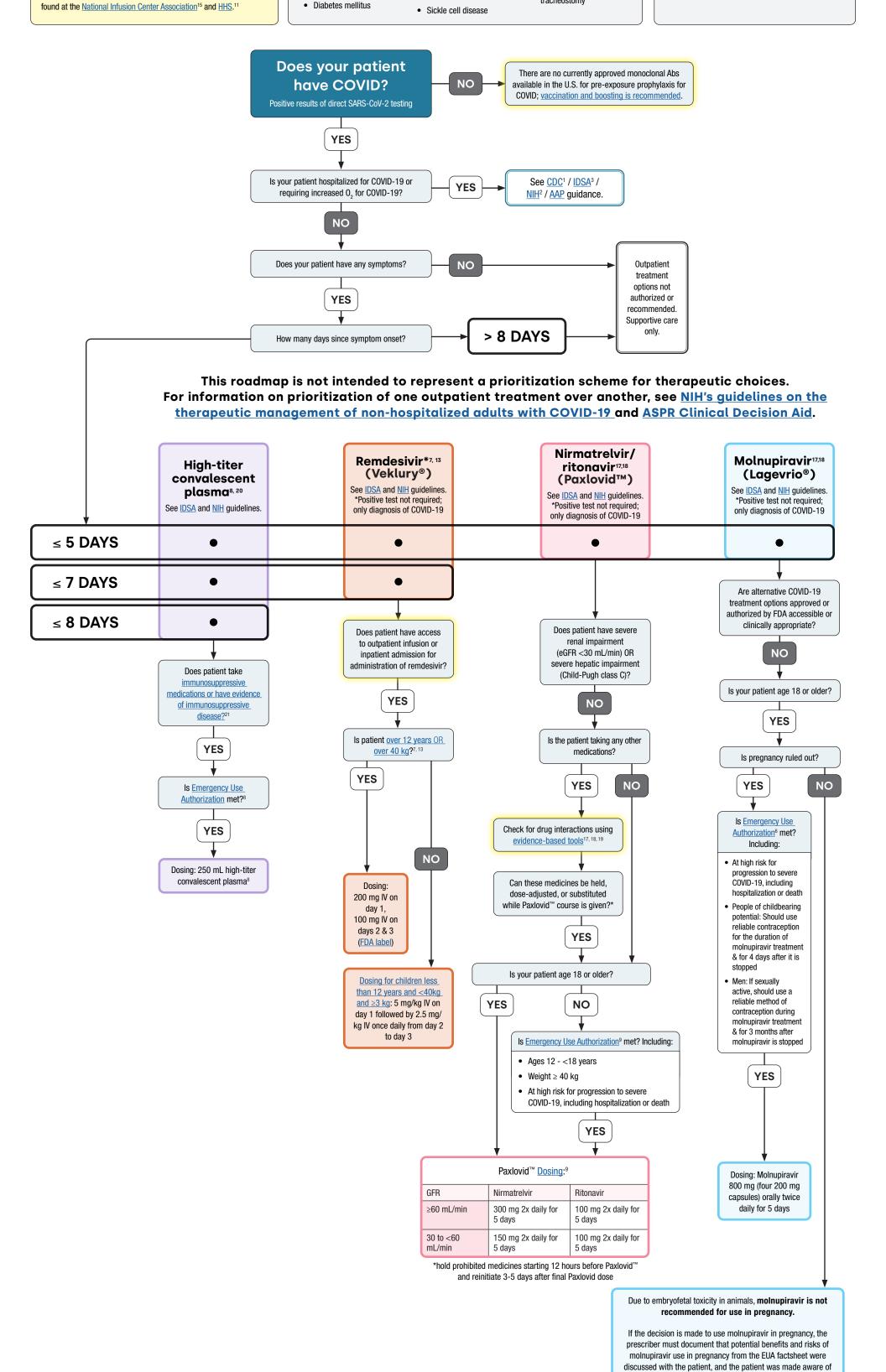
Included here are some medical conditions that may place patients at a higher risk for progression to severe COVID-19:

- · Age 65 years and older
- BMI of more than 25 kg/m²
- Pregnancy
- · Chronic kidney disease
- Immunosuppressing medications
 - hypertension · Chronic lung disease
 - Neurodevelopmental · Cardiovascular disease or
 - confer medical complexity

dependence, e.g.,

tracheostomy

- disorders or conditions that · Medical technological
- When giving products under Emergency **Use Authorization, providers must:**
- 1. Give patient fact sheet for patients.
- 2. Inform patient of alternatives to treatment. 3. Inform patient that this is an unapproved drug.



References

- CDC guidelines for clinical management: Management of Patients with Confirmed 2019-nCoV | CDC
- NIH guidelines: COVID-19 Treatment Guidelines (nih.gov)
- IDSA guidelines: IDSA Guidelines on the Treatment and Management of Patients with COVID-19 (idsociety.org)
- NIH Guidelines Panel's Statement on Drug Interactions with Paxlovid: Statement on Paxlovid Drug-Drug Interactions | COVID-19 Treatment Guidelines (nih.gov)
- Sotrovimab EUA fact sheet: SOTROVIMAB-EUA.PDF (gskpro.com)
- Molnupiravir EUA fact sheet: FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORI-ZATION FOR MOLNUPIRAVIR (fda.gov)
- Remdesivir (Veklury™) Package Insert (Prescribing Information) with the extended approval for outpatient use: veklury_pi.pdf (gilead.com)
- Convalescent Plasma EUA fact sheet and List of Tests and Cutoffs of High Titers (table on page 9): https:// www.fda.gov/media/141477/download
- 9. Paxlovid EUA Fact Sheet for Healthcare Providers: https://www.fda.gov/media/155050/download
- 10. CDC List of Medical Conditions with risk of progression to severe COVID-19: Patient-directed format: People with Certain Medical Conditions | CDC Healthcare provider format: Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers (cdc.gov)
- 11. HHS Therapeutics Locator: COVID-19 Therapeutics Locator (arcgis.com)
- 12. Bebtelovimab EUA fact sheet: Fact Sheet for Healthcare Providers: Emergency Use Authorization for Bebtelovimab
- 13. Remdesivir EUA fact sheet for use in CHILDREN weighing 3.5 kg to <40 kg OR those less than 12 years old weighing at least 3.5 kg, who are NOT HOSPITALIZED: EUA 046 Veklury (remdesivir) FS for HCPs (01212022)
- (fda.gov) 14. Combat COVID Website on Treatment Options: COVID-19 Resources For Healthcare Providers | combatCOVID.hhs.gov
- 15. National Infusion Center Association Website: National Infusion Center Association. Relates to the Access and Availability link.
- 16. FDA CDER Scientific Review Documents for COVID-19 Related EUAs: CDER Scientific Review Documents <u>Supporting Emergency Use Authorizations for Drug</u> and Biological Therapeutic Products | COVID-19 | FDA

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- 17. University of Liverpool COVID-19 Drug Interactions Page: https://www.covid19-druginteractions.org/ prescribing_resources
- 18. NIH guidance on therapies for high-risk non-hospitalized patients: https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-thera-

pies-for-high-risk-nonhospitalized-patients/

Merck's pregnancy surveillance program at 1-877-888-4231 or pregnancyreporting.msd.com.

- 19. IDSA guidance on nirmatrelvir/ritonavir (Paxlovid) and molnupiravir: https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-
- 20. Early Use of High-titer Convalescent Plasma in Outpatients Trial: Randomized Controlled Trial of Early Outpatient COVID-19 Treatment with High-Titer Convalescent Plasma (nih.gov)
- 21. IDSA guidance on outpatient use of convalescent plasma in immunosuppressed patients: https://www. idsociety.org/globalassets/idsa/practice-guidelines/ covid-19/treatment/idsa-covid-19-gl-tx-and-mgmt--convalescent-plasma-2022-02-03.pdf
- 22. FDA updates Sotrovimab emergency use authorization