

COVID -19 Early Treatment Update 2022

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Disclosures

I have no financial disclosures

Most of these medications are under EUA and not FDA approved

Remdesivir is the only FDA approved therapy for COVID-19

Credit goes to Dr MarkENZler from Mayo Clinic, Summitview Urgent Care in Yakima, Christina Augnst, Pharm D, Joshua Murdock, Pharm D , R Gandhi from Harvard Medical School , IDSA, John Hopkins, NIH, CDC for their expertise

COVID-19 treatment

- Treatment Guideline organizations
 - WHO (World Health Organization)
 - Infectious Diseases Society of America: IDSA (U.S.)
 - National Institute of Health (NIH): U.S.

WHO

IDSA

NIH

COVID-19
Clinical management

Living guidance
25 January 2021

Overview of COVID-19 Treatment Guidelines (Summary Table)

Version 4.0 (April 22, 2021)

Intervention	Arbitrary use: mild to moderate disease	Setting and severity of illness			
		Hospitalized mild to moderate disease without need for supplemental oxygen	Hospitalized severe but non-critical disease (eg, with an SpO ₂ of 90-94%)	Hospitalized critical disease (eg, with an SpO ₂ of 88-90%)	Hospitalized critical disease (eg, with an SpO ₂ of 88-90%)
1. Hydroxychloroquine (HCQ)*	NA	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)
2. AZD1225†	NA	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)
3. Lopinavir + ritonavir	NA	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)	Recommended against use (B)(B)(C)
4. Corticosteroids	NA	Supports against use (B)(C)(C)	Supports use (B)(B)(C) If dexamethasone is available, dexamethasone 6 mg daily for 10 days (dexamethasone may be used)**	Recommended use (B)(B)(C) If dexamethasone is available, dexamethasone 6 mg daily for 10 days (dexamethasone may be used)**	Recommended use (B)(B)(C) If dexamethasone is available, dexamethasone 6 mg daily for 10 days (dexamethasone may be used)**
5. Tocilizumab	NA	NA	Supports use (B)(B)(C) If tocilizumab is available, tocilizumab 8 mg/kg (maximum 16 g) daily for 14 days (tocilizumab may be used)**	Supports use (B)(B)(C) If tocilizumab is available, tocilizumab 8 mg/kg (maximum 16 g) daily for 14 days (tocilizumab may be used)**	Supports use (B)(B)(C) If tocilizumab is available, tocilizumab 8 mg/kg (maximum 16 g) daily for 14 days (tocilizumab may be used)**
6. Convalescent plasma	Recommended only in the context of a clinical trial (B)(congregates)	Supports against use (B)(B)(C)	Supports against use (B)(B)(C)	Supports against use (B)(B)(C)	Supports against use (B)(B)(C)
7. Remdesivir	NA	Supports against routine use (B)(B)(C)	Supports use (B)(B)(C)	Supports use (B)(B)(C)	Supports use (B)(B)(C)

DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
Hospitalized but Does Not Require Supplemental Oxygen	The Panel recommends against the use of dexamethasone (AII) or other corticosteroids (AII)* There is insufficient evidence to recommend either for or against the routine use of remdesivir. For patients who are at high risk of disease progression, the use of remdesivir may be appropriate.
Hospitalized and Requires Supplemental Oxygen	Use one of the following options: • Remdesivir** (e.g., for patients who require minimal supplemental oxygen) (BIIa) • Dexamethasone** plus remdesivir** (e.g., for patients who require increasing amounts of supplemental oxygen) (BII) • Dexamethasone* (when combination therapy with remdesivir cannot be used or is not available) (B)
Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation	Use one of the following options: • Dexamethasone* (A) • Dexamethasone* plus remdesivir** (BII) For patients who were recently hospitalized* with rapidly increasing oxygen needs and systemic inflammation: • Add either baricitinib* (BIIa) or tocilizumab* (BIIa) to one of the two options above
Hospitalized and Requires IMV or ECMO	For most patients: • Dexamethasone* (A) For patients who are within 24 hours of admission to the ICU: • Dexamethasone* plus tocilizumab* (BIIa)

COVID-19 Pandemic

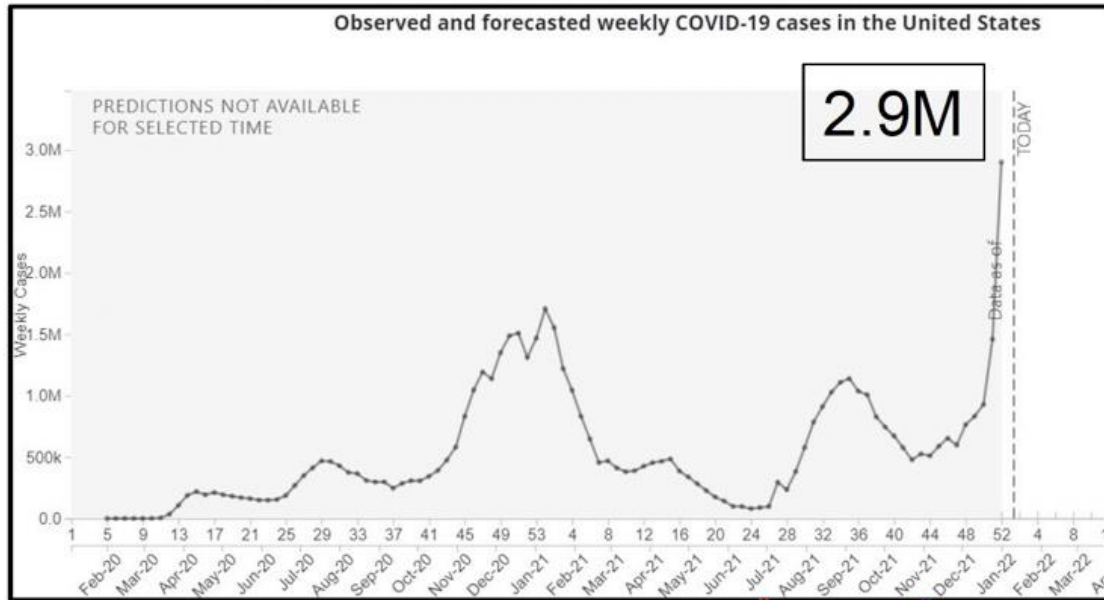
January, 2022: Covid-19 v. 3.0

- January, 2020
 - Start of Wuhan, China lockdown; First U.S. Death
- Burden (January 11, 2022)
 - World: > 312 M cases / > 5.5 M deaths
 - U.S. > 62 M cases
 - > 841,000 deaths
 - **1.36%** case fatality ratio (CFR)

Covid-19 cases / deaths: U.S.

CDC Covid-19 tracker: accessed January 10, 2022

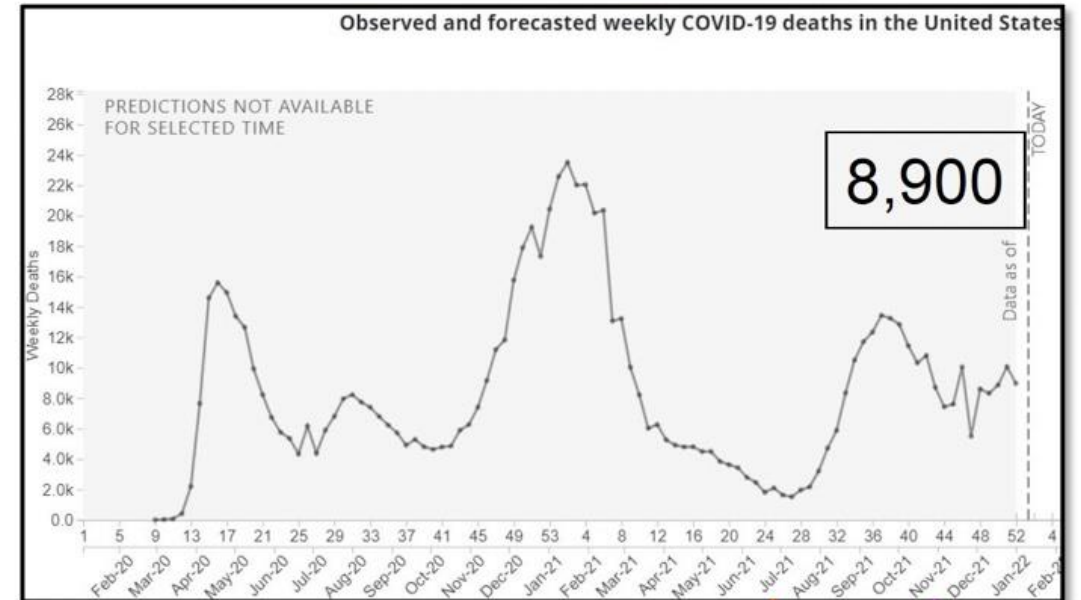
Weekly cases: U.S.



Delta

Omicron

Weekly deaths: U.S.

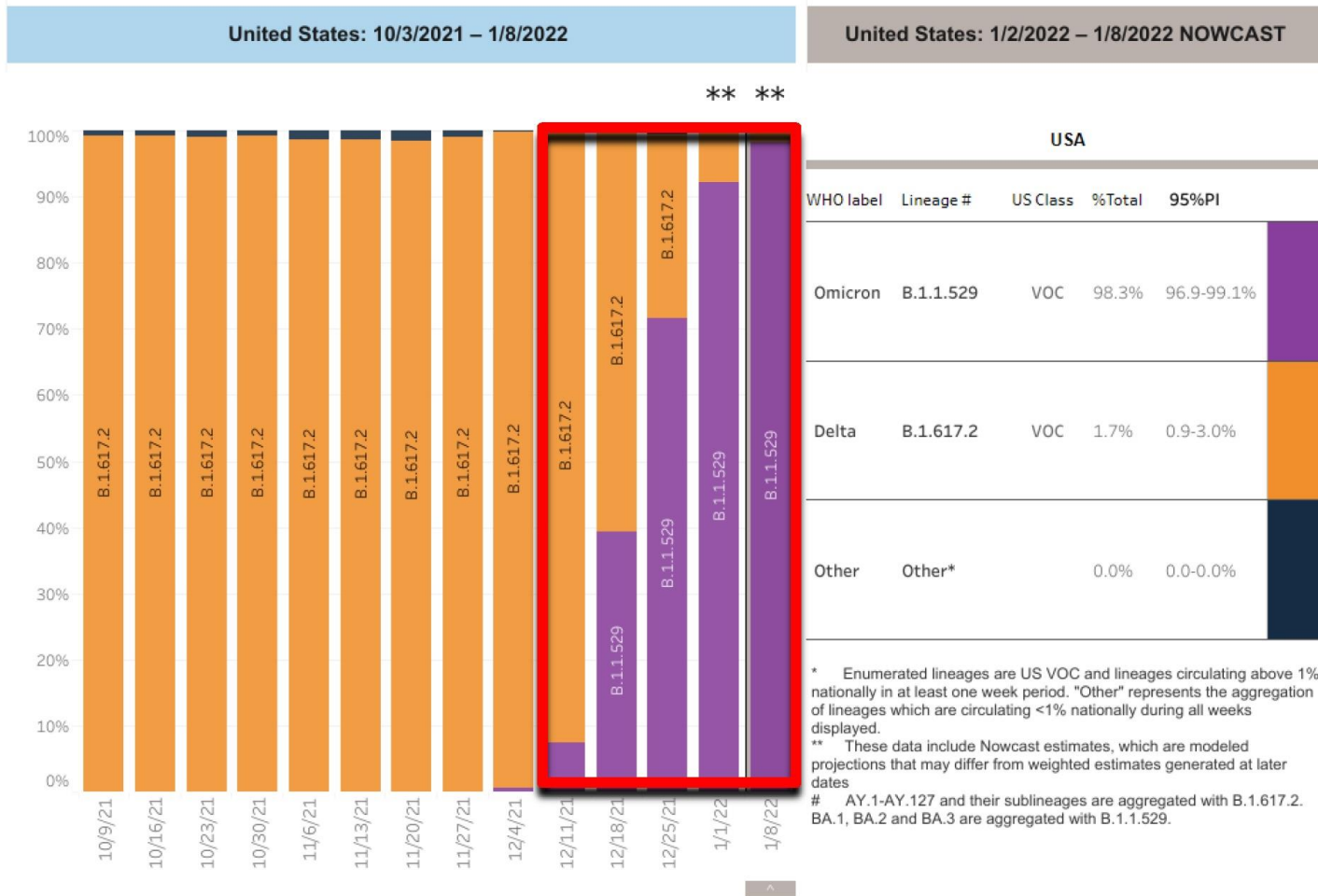


Delta

Omicron

U.S. Covid-19 variants by proportion

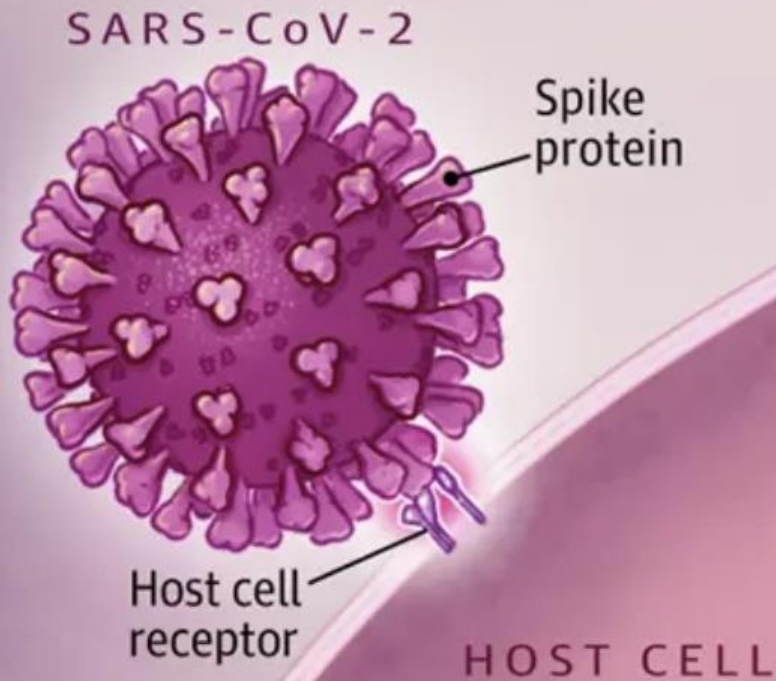
Accessed Jan. 11, 2022



Omicron: 96-99%
The predominant variant within 5 weeks!

Monoclonal antibodies are a therapy developed to treat viral infections including COVID-19.

SARS-CoV-2 uses a spike protein to attach to and enter human cells, which allows it to cause infection.



Monoclonal antibodies bind to the spike protein, prevent the virus from attaching to human cells, and tag it for destruction.

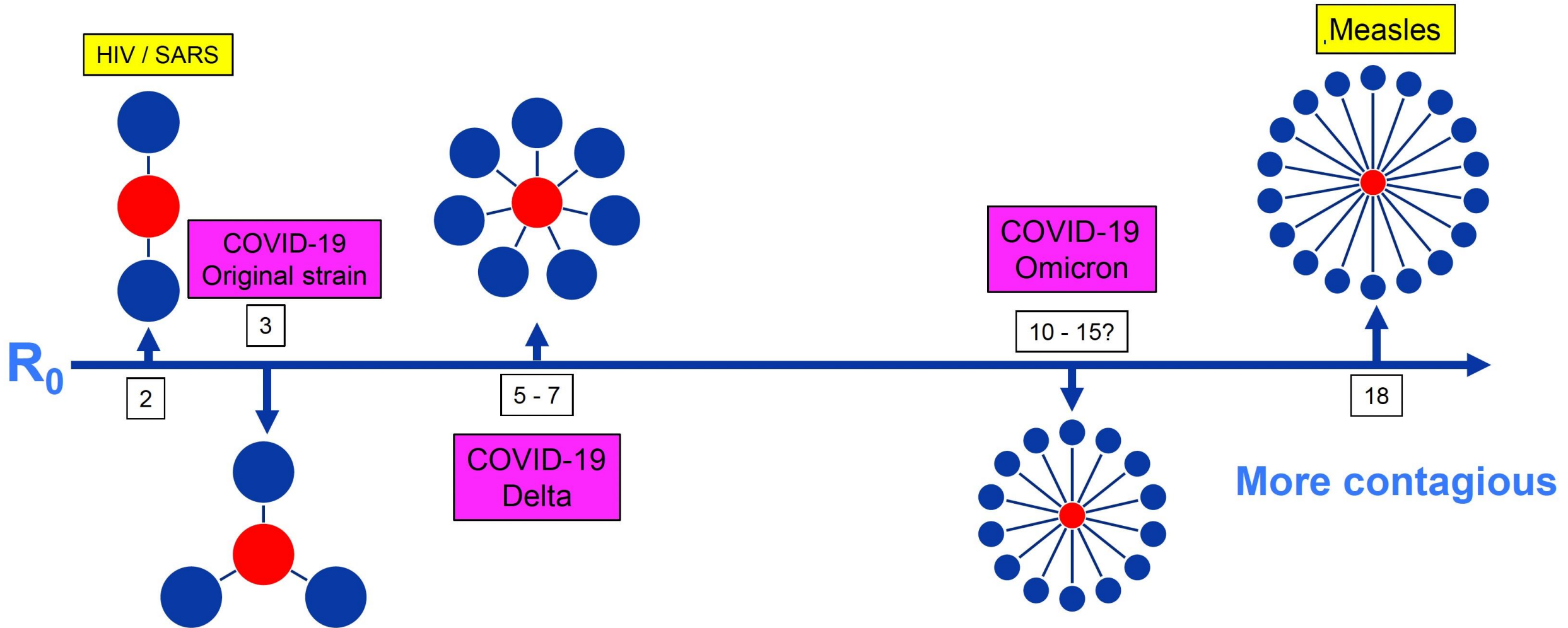


How monoclonal antibodies bind to SARS-CoV-2.

Source: [JAMA](#)

COVID-19 Infectivity

R_0 : the number of people 1 sick person will infect (on average)



COVID-19

Risks for disease progression and death (1-9%)

- **Age \geq 65 (75% of deaths)**
- Obesity: BMI > 35
- Chronic kidney disease
- Diabetes mellitus
- Immunocompromised: cancer, drugs (anti-CD20 etc), transplant
- Coronary artery disease / Cerebrovascular disease
- Hypertension
- Lung disease / COPD
- Pregnancy

Treatment across the Covid-19 Spectrum

Stage / severity	No Sx or pre-Sx	Mild illness	Moderate illness	Severe illness*	Critical illness (@ day 10-12)
	(+) PCR without symptoms	Mild symptoms (cough, fever taste/smell)	O ₂ sat ≥ 94%; pneumonia; dyspnea (@ day 5-8)	Sats < 94%, RR > 30; infiltrates > 50%	Resp failure, shock, organ dysfunction, ARDS
Frequency	?	80%		15%	5%
Viral phase	+	+++	+++	+	
Inflammation (CRP, DD, IL6)			++	+++	++
Potential Treatment					

Question 1

17 y.o. pregnant (28 weeks gestation) female

Itchy throat , cough, loss of taste x 2 days

Covid-19 PCR positive 2 days back.

Slight shortness of breath

What is the best outpatient treatment option?

IV remdesivir x 3 days

Molnupiravir, 800mg PO Bid x 5 days

Paxlovid(nirmatrelvir+ ritonavir) Bid for 5 days

Sotrovimab 500mg IV once

Question 2

What happens when MAB are administered

- 1) Reduction in adverse outcomes in low, but not high viral titer patients
- 2) Improved efficacy when used approximately 10 days after symptom onset
- 3) Decreased viral entry, VL and downstream effects when initiated early
- 4) Improved outcomes in patients receiving oxygen therapy due to COVID -19

COVID-19 NIH Treatment Panel Statement on treatment for High-risk, nonhospitalized patient with mild to moderate covid-19

Aged ≥ 12 years and ≥ 40 kg

Sotrovimab 500mg IV once (w/i 10d)

Paxlovid(nirmatrelvir 300mg plus ritonavir 100mg) PO Bid for 5 days (w/i 5d)

Remdesivir, IV: 200mg once then 100mg daily x 2 (w/i 7d).

Aged ≥ 18 years & above not available

Molnupiravir, 800mg Bid for 5 days (w/i 5d)

Outpatient therapy options: Summary

Nonhospitalized mild-moderate Covid-19 at high-risk for progression

Agent	Class / EUA date	Dose / route / Sx duration / common side effect	RCT Data (n)	Comments
Sotrovimab (GSK)	MoAB: broad anti-SARS / 5/26/21	IV: 500mg Sx ≤ 10d	COMET-ICE ¹ : (583); Covid vaccine status not specified; reduced H/D by 79%: 1% vs. 7%; p=0.002 (6/2021)	≥ 12y.o. & ≥ 40kg HHS purchased \$1B

MoAB = monoclonal antibody; Sx = symptom; H = hospitalization; D = death; EUA = emergency use authorization

Covid-19 Monoclonal antibodies (IV)

Decrease risk hospitalization / death: high risk w/i 10d Sx

Product / manufacturer / dose (mg)	Manufacturer / EUA date	Distributed by HHS?	Trials	Variant activity	Comments
Bamlanivimab 700mg	Lilly 11/2020	Y	Poor: gamma & beta	Inactive Delta	HHS halt use 6/25/21
Bamlanivimab / etesevimab / 700 - 1400	Lilly Feb. 2021	Y	Poor: gamma & beta	Inactive Delta	HHS halt use 6/25/21

Anti-spike protein monoclonal antibodies (IV)

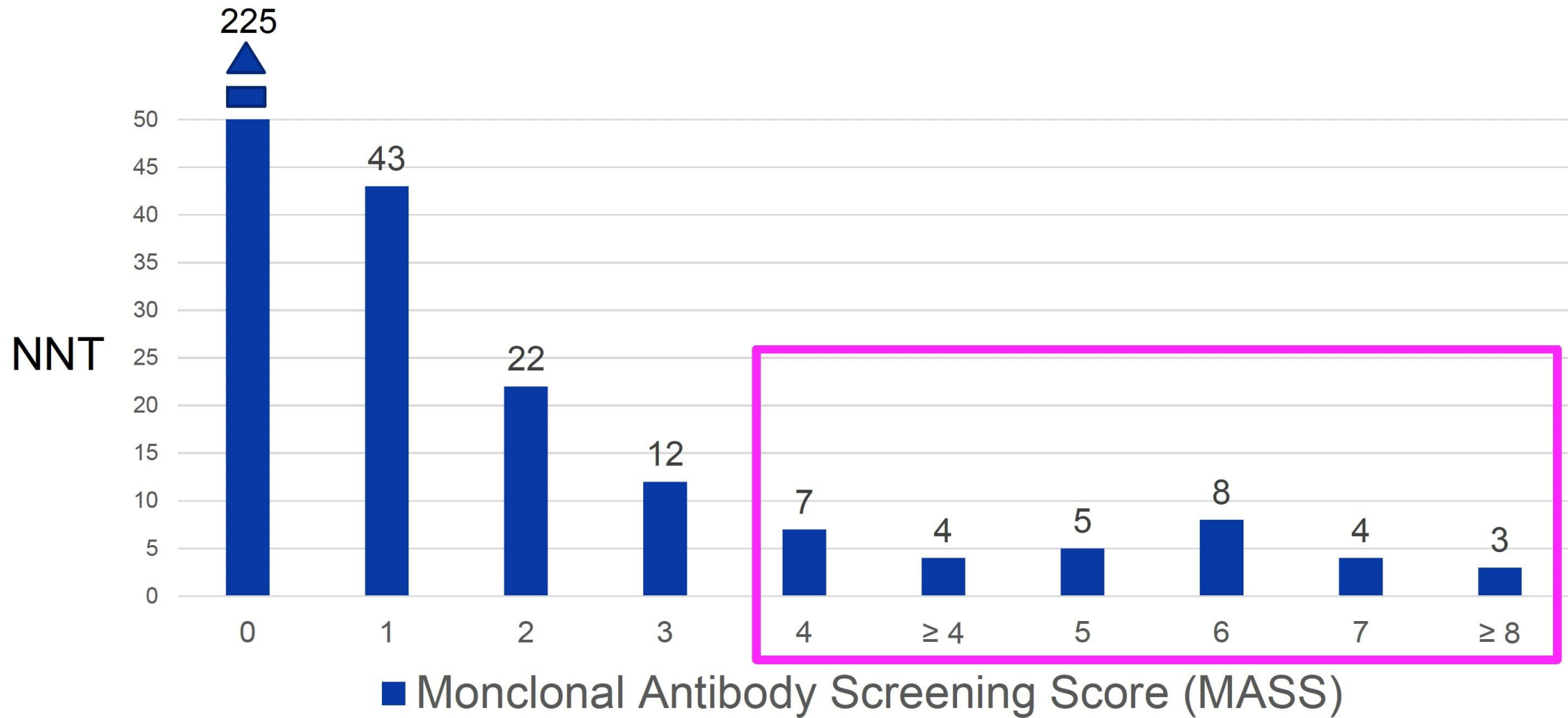
Target receptor-binding domain of spike protein, blocking viral entry into host cells

- Mayo: **Monoclonal Antibody Rx Team (MATRx)**: screen COVID (+) PCR mild-moderate Covid & high risk for progression: **start 11/2020**
 - **Age \geq 65**
 - Any age: BMI > 35; CKD; diabetes
 - ICH: cancer, drugs, transplant, etc
 - **Age \geq 55 AND CV disease; HTN; or COPD / other respiratory**
 - Adolescents with risks
- Mayo Enterprise: > 20,000 patients (12/21), most w/i 3d Dx
 - Developed **MASS comorbidity score**: to stratify who benefits the most for MoAB therapy

Monoclonal Antibody Screening Score (MASS): Mayo Clinic*

≥ 65 years of age (2)	≥ 55 years of age	≥ 18 years of age
<ul style="list-style-type: none">• No additional requirements	<ul style="list-style-type: none">• Cardiovascular Disease (2)• Hypertension (1)• COPD/other chronic respiratory disease (3)	<ul style="list-style-type: none">• BMI ≥ 35 kg/m² (1)• Chronic Kidney Disease (3)• Diabetes (2)• Immunosuppressive disease or receiving immunosuppressive treatment (4)

Covid-19 monoclonal antibody treatment outcome by Monoclonal Antibody Screening Score (MASS)¹



Outpatient therapy options: Summary

Nonhospitalized mild-moderate Covid-19 at high-risk for progression

Agent	Class / EUA date	Dose / route / Sx duration / common side effect	RCT Data (n)	Comments
Sotrovimab (GSK)	MoAB: broad anti-SARS / 5/26/21	IV: 500mg Sx ≤ 10d	COMET-ICE ¹ : (583); Covid vaccine status not specified; reduced H/D by 79%: 1% vs. 7%; p=0.002 (6/2021)	≥ 12y.o. & ≥ 40kg HHS purchased \$1B
Nirmatrelvir / ritonavir (Paxlovid) Pfizer	Antiviral: N = protease inhibitor; R = booster 12/22/21	300/100mg Bid PO x 5d Sx ≤ 5 days Dysgeusia, diarrhea, HTN, myalgia	EPIC-HR ² . n=2085 unvaccinated; 88% effective reducing H/D vs. placebo (Sx w/i 3-5d): 0.8% (no deaths) vs. 7.0% (7 deaths): placebo p< 0.0001; (11/8/21)	≥ 12y.o. & ≥ 40kg Dose adjust CrCl 30- 60; avoid < 30 Drug-drug interactions Avoid: liver ≥ Child C Pregnancy: no data
Remdesivir (Veklury®) Gilead	Antiviral / FDA approved outpatient 1/21/22	IV 200mg/100/100: d 1, 2, & 3 Sx ≤ 7 d	PINETREE ³ : (562) unvaccinated; 87% lower H/D 0.7% vs. 5.3% HR 0.13; 95% CI 0.03, 0.59, p=0.008 (12/22/21)	FDA EUA Peds ≥ 3.5kg
Molnupiravir (Lagevrio) (200mg tab) Merck Last Choice	Antiviral: nucleoside analogue / 12/23/21	PO: 800mg Bid x 5d / Sx ≤ 5d Nausea / diarrhea / dizziness	MOVE-OUT. (1433) unvaccinated. 6.8% vs. 9.7% H/D Abs RR 3.0% Rel RR 30% (RR 0.7; CI 0.49, 0.99): no p reported; 12/6/21	≥ 18 y.o. Potential fetal harm Avoid: lactation/PG Men: barrier prot x 3mo No dose adjust.

MoAB = monoclonal antibody; Sx = symptom; H = hospitalization; D = death; EUA = emergency use authorization

¹COMET-ICE Trial: Sotrovimab. Gupta AG et al. NEJM 2021;385:1941

²Paxlovid EPIC-HR Trial: *BMJ* 2021;375:n2713

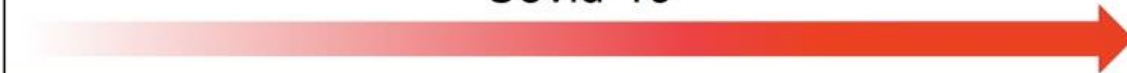
³Remdesivir trial: Gottlieb RL et al. NEJM Dec. 22, 2021

MOVE-OUT trial, Molnupiravir: Bernal et al. NEJM Dec. 16, 2021⁴

Covid-19 Infection management

Mild-moderate
Covid-19, high risk progression

Severe-to-critical (hospitalized)
Covid-19



Pre-hospital¹

Nirmatrelvir-ritonavir
(Paxlovid) 300/100mg PO Bid
x 5d

Sotrovimab² 500mg IV once

IV remdesivir
x 3d

Molnupiravir 800mg PO Bid
x 5d

Antiviral

Remdesivir

X 5 days

Immune modulators

Dexamethasone

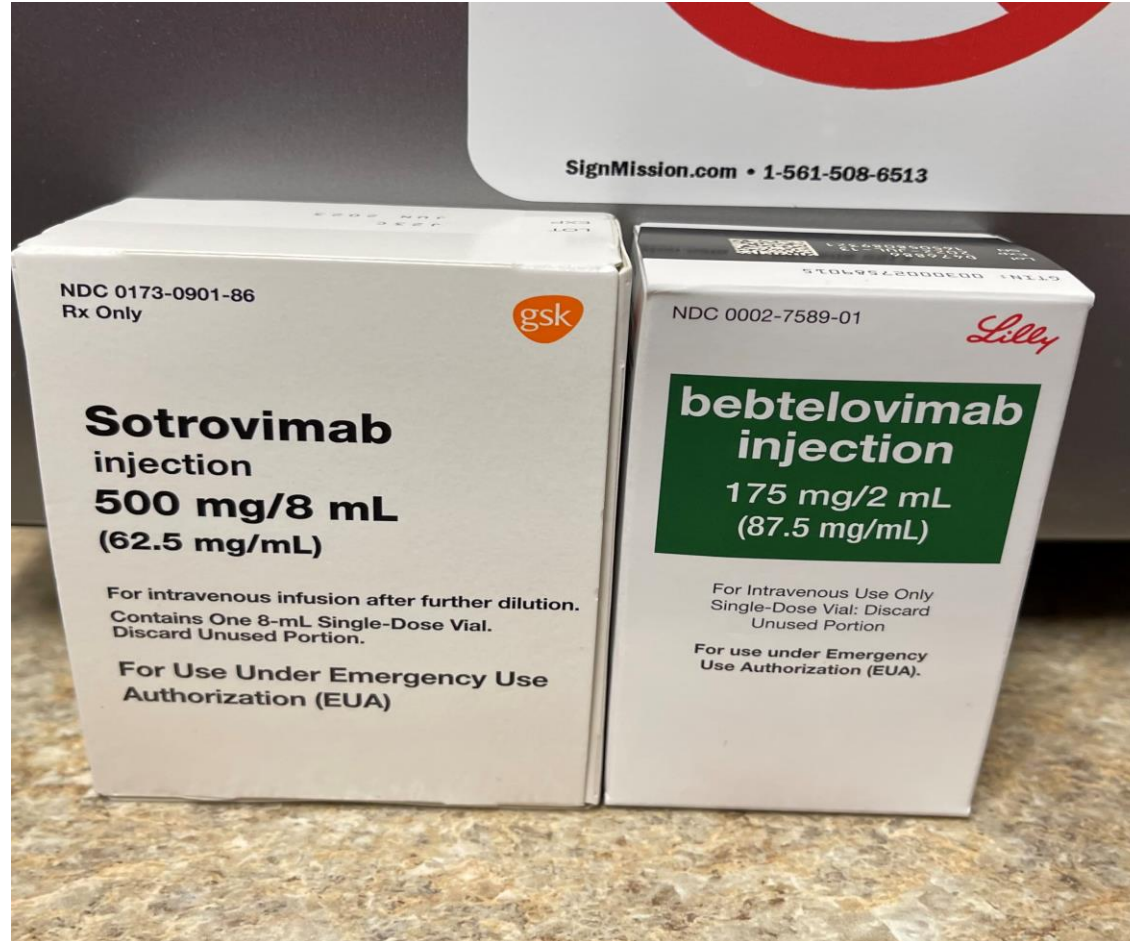
Tocilizumab
8mg/kg IV once

Baricitinib
4mg PO QD 1-14d

¹Start w/i 5 days symptom onset: Paxlovid & Molnupiravir; 10 days sotrovimab; 7 days remdesivir

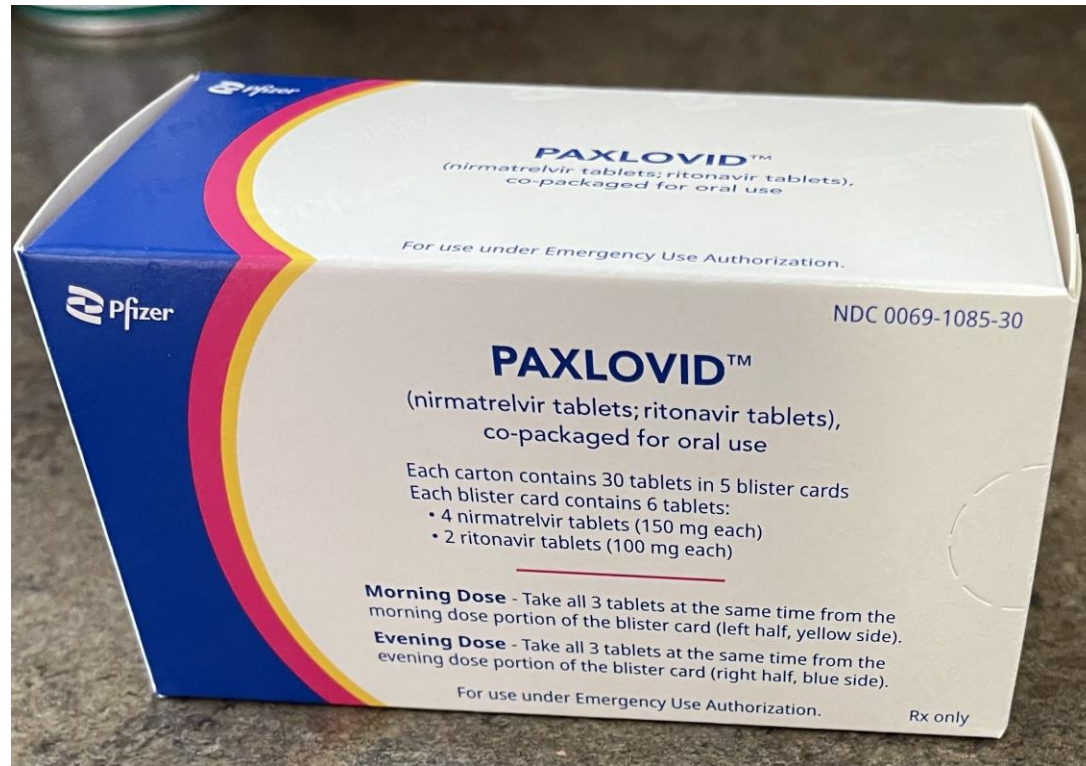
²Bamlanivimab / etesevimab and casirivimab / imdevimab: ineffective vs. omicron variant

INJECTABLE MONOCLONAL ANTIBODIES


















ORAL PILLS FOR OUTPATIENT TREATMENT OF MILD- MODERATE COVID-19



10 Things to Know About COVID-19 Antiviral Pills

	PAXLOVID	MOLNUPIRAVIR
1 What is it?	 <p>1 ritonavir 2 nirmatrelvir</p>	 <p>4 molnupiravir</p>
2 Who makes it?		
3 How does it work?	Blocks a protein the virus uses to multiply	Inserts itself into the virus's genetic material
4 Who can take it?	Adults & kids 12+ weighing 88+ lbs & at high risk 	Adults 18+ at high risk* 
5 How effective is it?	 <p>Lowers risk by almost 90%</p>	 <p>Lowers risk by about 30%</p>
6 Are there any drug interactions?	Many statins, blood thinners, hormonal birth controls, some seizure medications, St. John's wort**	Minimal
7 How much does it cost?	\$530	\$700
	Currently free to applicable patients during the COVID-19 public health emergency	
8 How do you take it?	<p>AM </p> <p>PM </p>	<p>2x daily by mouth for 5 days</p> <p> AM</p> <p> PM</p>
9 What does it treat?	<p>MILD MODERATE SEVERE</p>	
10 How can you get it?	<p>Prescription only</p> 	

* Should only be used when no other treatment is available for mild to moderate COVID-19.
** Consult your doctor for other potential drug interactions.

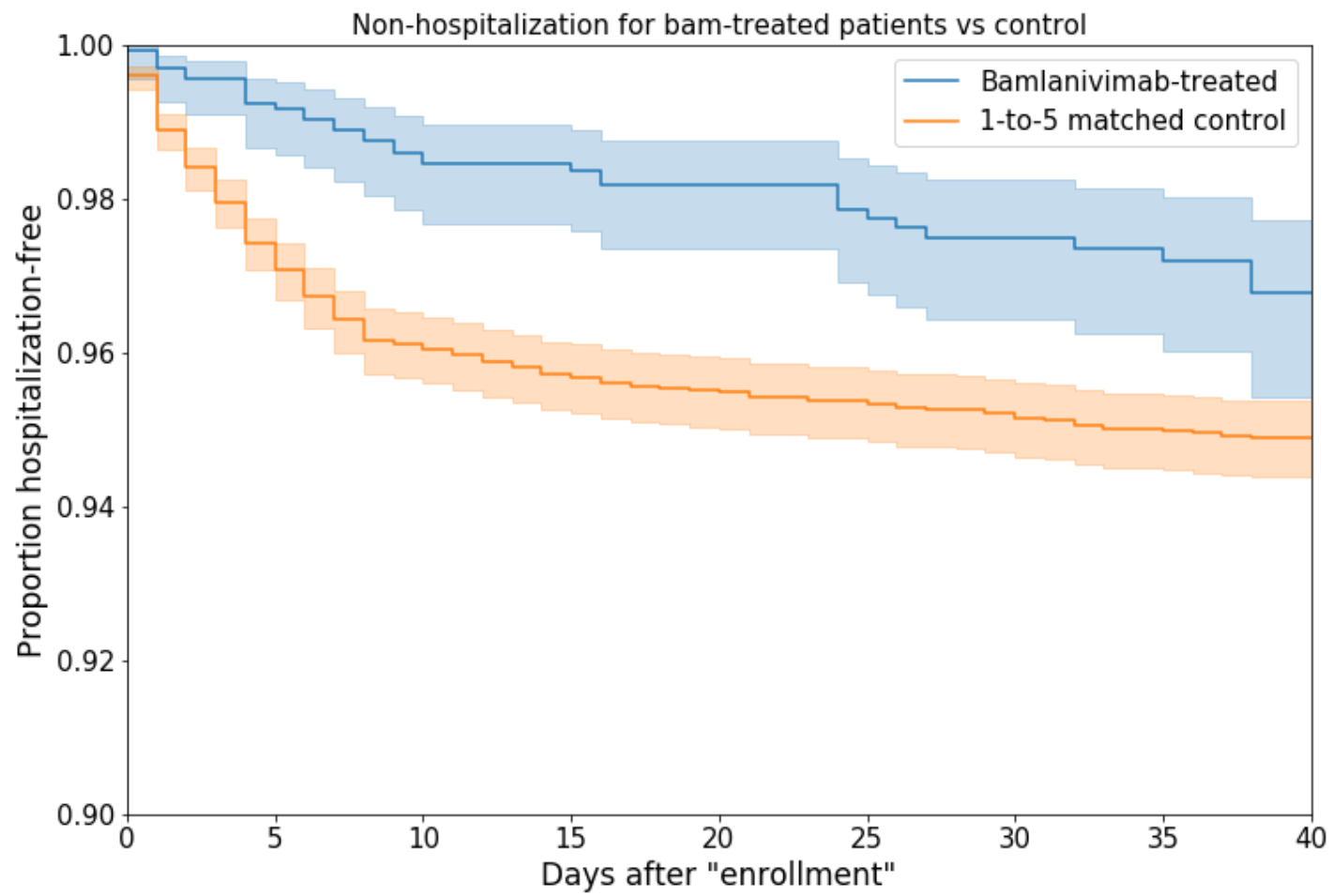
<p>Prescribe an alternative COVID-19 therapy for patients who are receiving any of the medications listed.</p>	<p>Before prescribing ritonavir-boosted nirmatrelvir (Paxlovid), determine whether the patient is receiving any of the medications listed.</p> <ul style="list-style-type: none"> • If the patient is receiving any of these medications, withhold the medication if clinically appropriate. • If withholding is not clinically appropriate, use an alternative concomitant medication or COVID-19 therapy.^a
<ul style="list-style-type: none"> • Amiodarone • Apalutamide • Bosentan • Carbamazepine • Cisapride • Clopidogrel • Clozapine • Colchicine in patients with renal and/or hepatic impairment • Disopyramide • Dofetilide • Dronedarone • Eplerenone • Ergot derivatives • Flecainide • Flibanserin • Glecaprevir/pibrentasvir • Ivabradine • Lumateperone • Lurasidone • Mexiletine • Phenobarbital • Phenytoin • Pimozide • Propafenone • Quinidine • Ranolazine • Rifampin • Rifapentine • Rivaroxaban • Sildenafil for pulmonary hypertension • St. John's wort • Tadalafil for pulmonary hypertension • Ticagrelor • Vorapaxar 	<ul style="list-style-type: none"> • Alfuzosin • Alprazolam • Atorvastatin • Avanafil • Clonazepam • Codeine • Cyclosporine^b • Diazepam • Everolimus^b • Fentanyl • Hydrocodone • Lomitapide • Lovastatin • Meperidine (pethidine) • Midazolam (oral) • Oxycodone • Piroxicam • Propoxyphene • Rosuvastatin • Salmeterol • Sildenafil for erectile dysfunction • Silodosin • Simvastatin • Sirolimus^b • Suvorexant • Tacrolimus^b • Tadalafil for erectile dysfunction • Tamsulosin • Tramadol • Triazolam • Vardenafil

^a Expert consultation may be considered. In some cases, dose reduction of the concomitant medication may be an appropriate management strategy.

Figure 1. Therapeutic Management of Nonhospitalized Adults With COVID-19

PATIENT DISPOSITION	PANEL'S RECOMMENDATIONS
<p>Does Not Require Hospitalization or Supplemental Oxygen</p>	<p>All patients should be offered symptomatic management (AIII).</p> <p>For patients who are at high risk of progressing to severe COVID-19^a (treatments are listed in order of preference based on efficacy and convenience of use):</p> <ul style="list-style-type: none"> • Ritonavir-boosted nirmatrelvir (Paxlovid)^{b,c} (AIIa) • Sotrovimab^d (AIIa) • Remdesivir^{c,e} (BIIa) • Molnupiravir^{c,f} (CIIa) <p>The Panel recommends against the use of dexamethasone or other systemic corticosteroids in the absence of another indication (AIII).^g</p>
<p>Discharged From Hospital Inpatient Setting in Stable Condition and Does Not Require Supplemental Oxygen</p>	<p>The Panel recommends against continuing the use of remdesivir (AIIa), dexamethasone^g (AIIa), or baricitinib^g (AIIa) after hospital discharge.</p>
<p>Discharged From Hospital Inpatient Setting and Requires Supplemental Oxygen</p> <p><i>For those who are stable enough for discharge but who still require oxygen^h</i></p>	<p>There is insufficient evidence to recommend either for or against the continued use of remdesivir or dexamethasone.</p>
<p>Discharged From ED Despite New or Increasing Need for Supplemental Oxygen</p> <p><i>When hospital resources are limited, inpatient admission is not possible, and close follow-up is ensuredⁱ</i></p>	<p>The Panel recommends using dexamethasone 6 mg PO once daily for the duration of supplemental oxygen (dexamethasone use should not exceed 10 days) with careful monitoring for AEs (BIII).</p> <p>Since remdesivir is recommended for patients with similar oxygen needs who are hospitalized,^j clinicians may consider using it in this setting. Given that remdesivir requires IV infusions for up to 5 consecutive days, there may be logistical constraints to administering remdesivir in the outpatient setting.</p>

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion



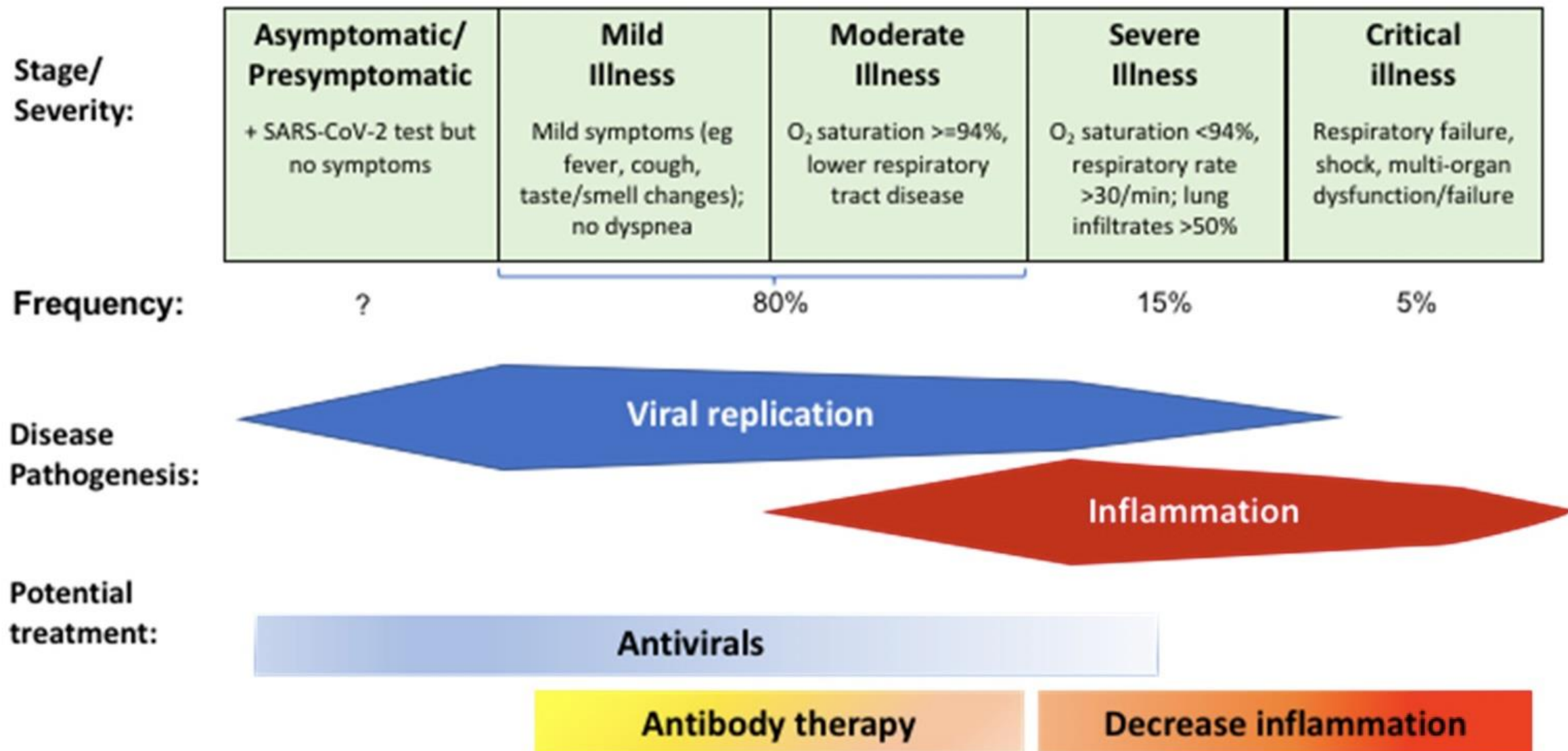
Conclusions: Mayo Monoclonal Antibody Program

Effective and safe treatment option for high-risk patients with mild to moderate covid-19 in outpatient setting

Program and process: multidisciplinary team, active > passive approach model, support of leadership, partnership with primary providers, physical and electronic infrastructure, flexibility and adaptability (mobile units, underserved persons)

Real-time assessment of clinical outcomes to further guide our practice implementation

Management Across the COVID-19 Spectrum



Antiviral Effect of Monoclonal Antibodies

- In outpatients with mild to moderate COVID-19, bamlanivimab and casirivimab + imdevimab appear to accelerate decline in SARS CoV-2 level compared to placebo

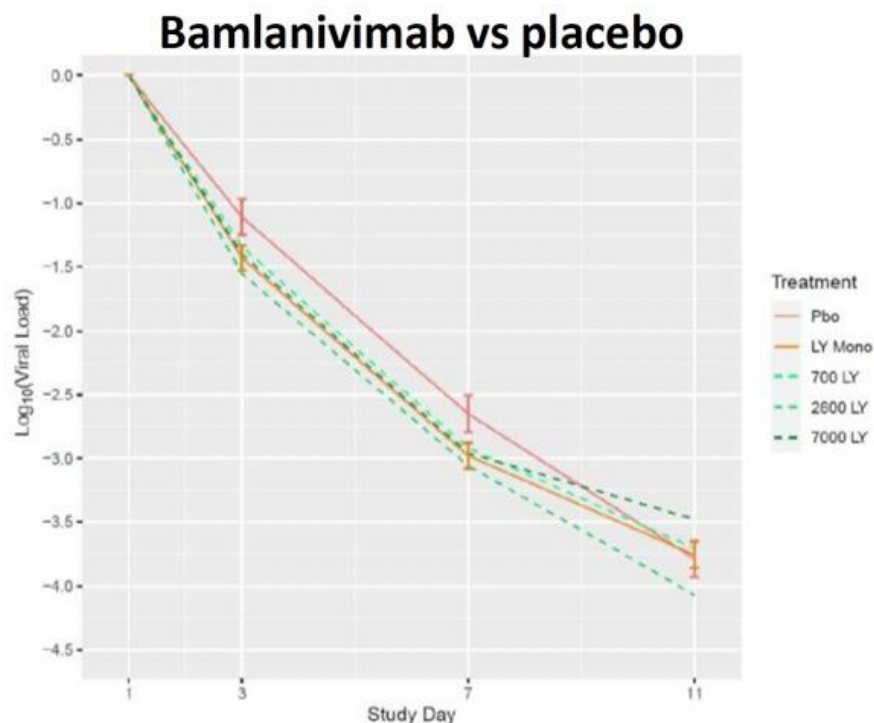
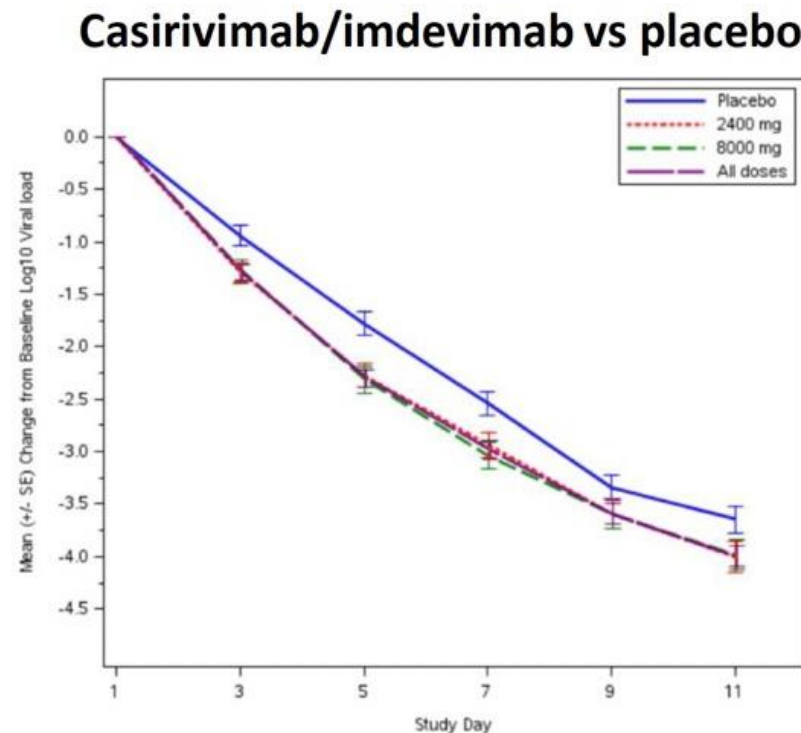


Figure 1: SARS-CoV-2 viral load change from baseline by visit.

Difference statistically significant for intermediate dose



Largest reduction in viral load in participants seronegative at baseline

Bamlanivimab

- In outpatients with mild to moderate disease (n=452) enrolled within 3 days of positive SARS-CoV-2 test, lower rate of ED visits/hospitalization in those who received bamlanivimab vs. placebo, particularly among high-risk patients
- Time to symptom improvement: median 6 days with antibody, 8 days with placebo
- Safety of antibody and placebo appeared to be similar

Hospitalization/ED Visit: All Participants			
Treatment	N	Events	Proportion
Placebo	156	9	6%
700 mg	101	1	1%
2800 mg	107	2	2%
7000 mg	101	2	2%
Pooled antibody	309	5	2%

Hospitalization/ED Visit: Participants at Higher Risk of Hospitalization			
Treatment	N	Events	Proportion
Placebo	69	7	10%
700 mg	46	1	2%
2800 mg	46	1	2%
7000 mg	44	2	5%
Pooled antibody	136	4	3%

Casirivimab/Imdevimab (C/I)

- In outpatients with mild to moderate disease (n=799) enrolled within 3 days of positive SARS-CoV-2 test, lower rate of hospitalization/ED visit in those who received casirivimab/imdevimab vs. placebo, particularly among high-risk patients
- Median time to symptom improvement: 5 days with C/I and 6 days with placebo
- Safety of antibodies and placebo similar
 - 1 anaphylactic reaction, 4 infusion reactions (8000 mg group)

Hospitalization/ED Visit: All Participants			
Treatment	N	Events	Proportion
Placebo	231	10	4%
C/I 2400 mg	215	4	2%
C/I 8000 mg	219	4	2%
Pooled antibody	434	8	2%

Hospitalization/ED Visit: Participants at Higher Risk of Hospitalization			
Treatment	N	Events	Proportion
Placebo	78	7	9%
C/I 2400 mg	70	2	3%
C/I 8000 mg	81	2	2%
Pooled antibody	151	4	3%

Patients with Multiple Risk Factors Appear to be at Greatest Risk

COVID-NET: Adjusted rate ratios for COVID-19 Hospitalization

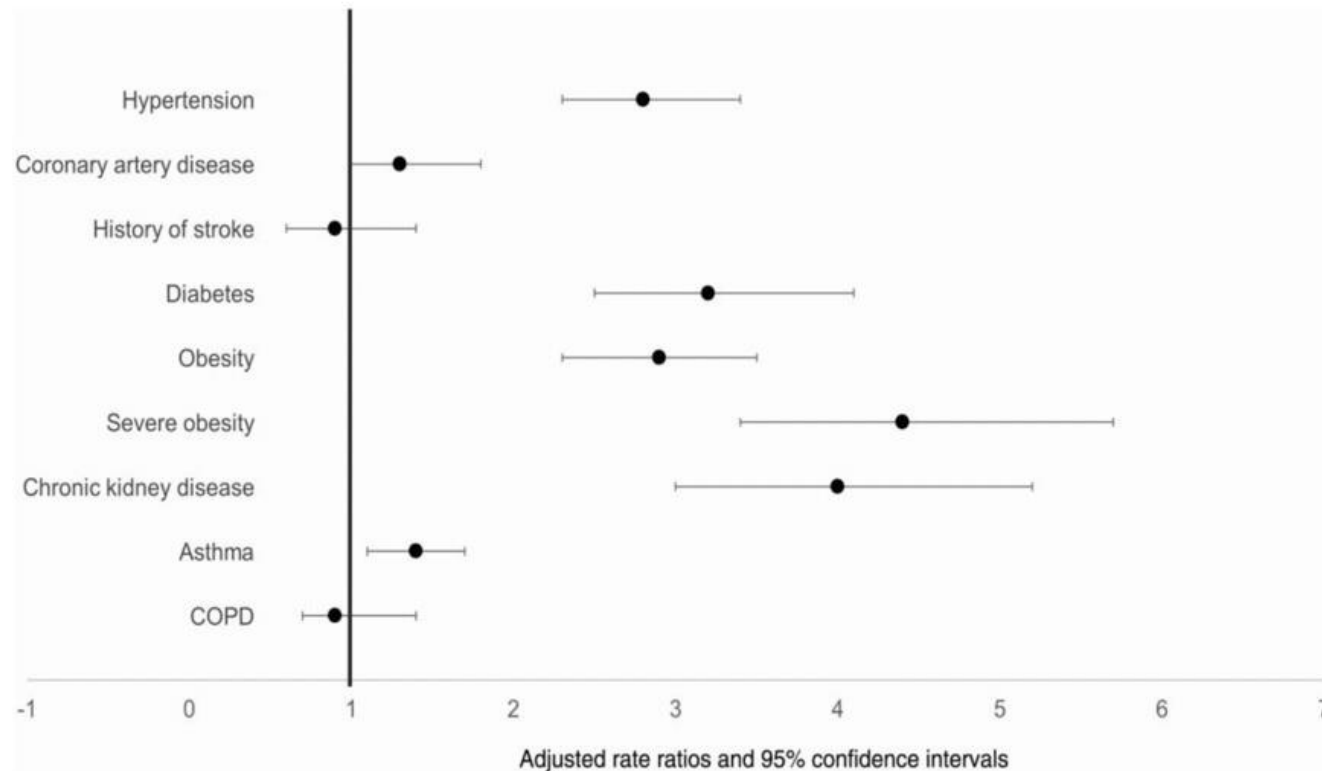


Table 3. Unadjusted and Adjusted^a Rate Ratios for Number of Underlying Medical Conditions and Hospitalization for Coronavirus Disease 2019 (COVID-19), COVID-19–Associated Hospitalization Surveillance Network, 1 March–23 June 2020

Characteristic	Unadjusted RR (95% CI)	Adjusted RR ^a (95% CI)
No. of conditions^b		
1	2.8 (2.7–3.1)	2.5 (2.1–3.0)
2	5.6 (5.2–6.1)	4.5 (3.7–5.5)
≥3	7.2 (6.6–7.9)	5.0 (3.9–6.3)
Age 45–64 y^c		
Age ≥65 y ^c	...	1.8 (1.5–2.2)
Age ≥65 y^c		
Male sex ^d	...	2.6 (2.1–3.1)
Male sex^d		
Non-Hispanic black ^e	...	1.2 (1.1–1.4)
Non-Hispanic black^e		
Other race/ethnicity ^e	...	3.9 (3.3–4.7)
Other race/ethnicity^e		
Other race/ethnicity ^e	...	3.3 (2.8–3.9)

Abbreviations: CI, confidence interval; RR, rate ratio.

^aModel for number of conditions (variable) is adjusted for age, sex, and race/ethnicity.

^bReference group is no underlying medical condition; number of conditions is a sum of underlying medical conditions excluding hypertension; the most recent year of available Behavioral Risk Factor Surveillance System data for hypertension was 2017.

^cReference group is 18–44 years.

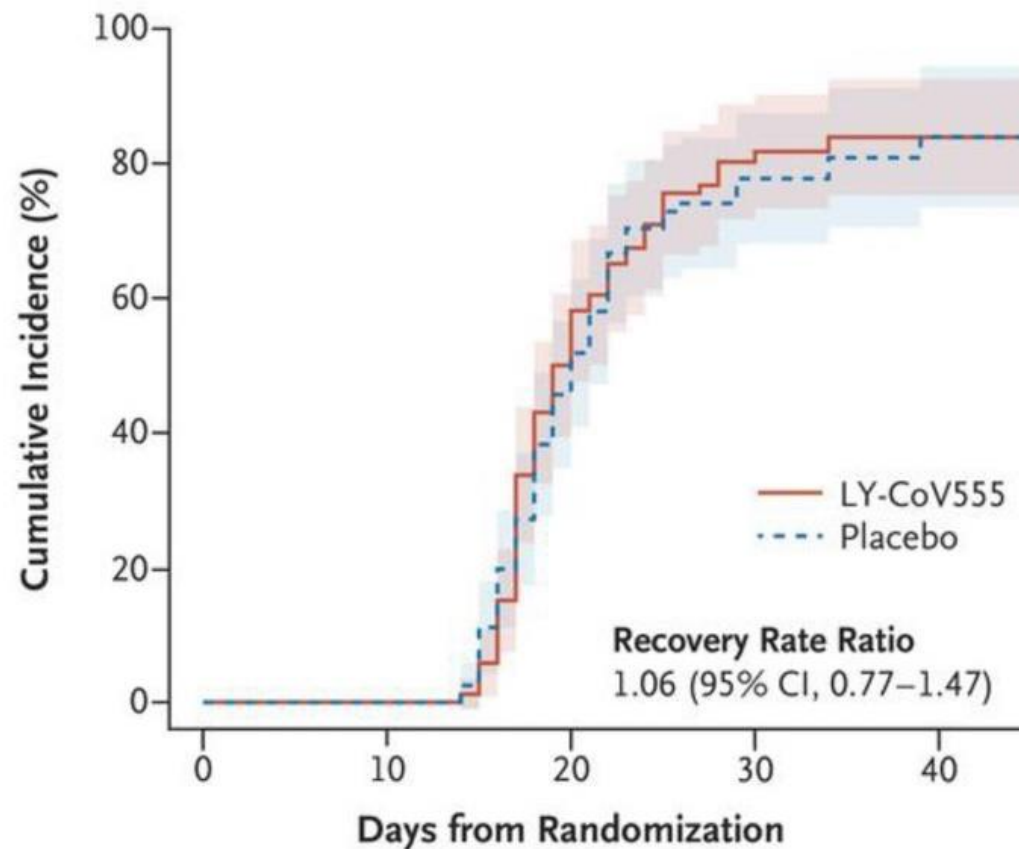
^dReference group is female.

^eReference group is non-Hispanic white.

Bamlanivimab in Hospitalized Patients

- Hospitalized patients with COVID-19 and without end organ failure randomized 1:1 to receive LY-CoV555 or placebo (ACTIV-3)
- Stopped for futility after 314 participants enrolled: no evidence for efficacy of the antibody

B Time to Sustained Recovery



No. at Risk	0	10	20	30	40
LY-CoV555	87	86	41	9	3
Placebo	81	81	41	10	4

REGN-COV2 in Hospitalized Patients

REGN-COV2 INDEPENDENT DATA MONITORING COMMITTEE RECOMMENDS HOLDING ENROLLMENT IN HOSPITALIZED PATIENTS WITH HIGH OXYGEN REQUIREMENTS AND CONTINUING ENROLLMENT IN PATIENTS WITH LOW OR NO OXYGEN REQUIREMENTS

TARRYTOWN, N.Y., Oct. 30, 2020 /PRNewswire/ --

December 29, 2020 at 4:30 PM EST

REGENERON ANNOUNCES ENCOURAGING INITIAL DATA FROM COVID-19 ANTIBODY COCKTAIL TRIAL IN HOSPITALIZED PATIENTS ON LOW-FLOW OXYGEN

TARRYTOWN, N.Y., Dec. 29, 2020 /PRNewswire/ --

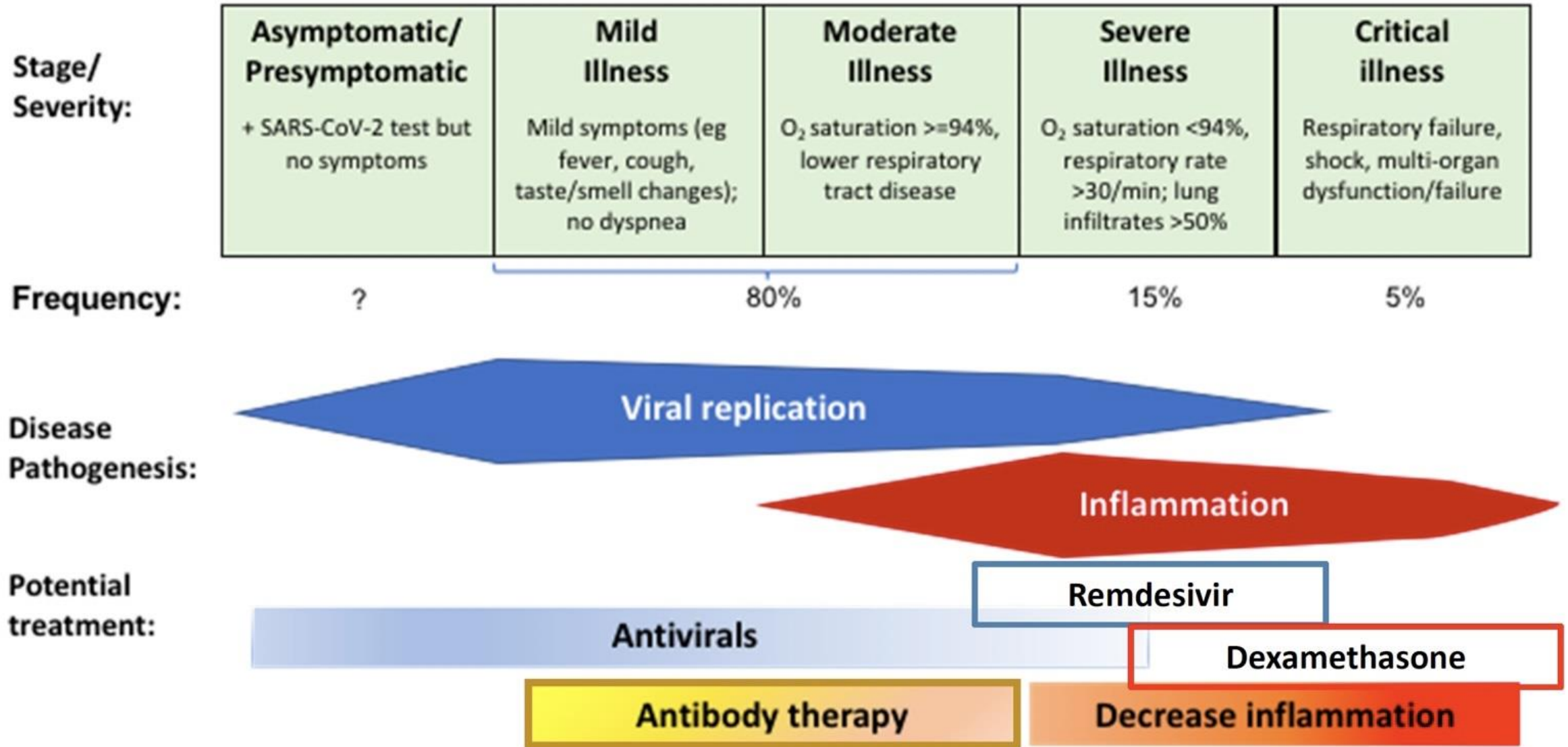
Phase 3 program in hospitalized patients to continue based on passing futility analysis on ability to reduce incidence of death or mechanical ventilation

As in earlier outpatient trial, immune status when patients entered the trial was a strong predictor of viral load and clinical outcomes

First antibody therapy to demonstrate anti-viral effect in patients hospitalized with COVID-19

- EUA recommends against Casirivimab/Imdevimab in patients who are hospitalized for COVID-19 or who require oxygen therapy due to COVID-19
- REGN-COV2 still being evaluated in hospitalized patients in the RECOVERY trial and in ongoing trial in people on low flow oxygen

Management Across the COVID-19 Spectrum



Q1 Answer: COVID-19 outpatient treatment:
pregnancy Early COVID-19 infection

Pregnant patients are at high risk for COVID-19
progression

Sotrovimab is the treatment of choice for pregnancy

IV **remdesivir** for 3 days could be an alternative treatment
choice IF sotrovimab is unavailable.

There are no pregnancy data for **Paxlovid**.

Molnupiravir is contraindicated in pregnancy & < 18 y.o.

Question 2

What happens when MAB are administered

- 1) Reduction in adverse outcomes in low, but not high viral titer patients
- 2) Improved efficacy when used approximately 10 days after symptom onset
- 3) Decreased viral entry, VL and downstream effects when initiated early
- 4) Improved outcomes in patients receiving oxygen therapy due to COVID -19

COVID-19 Selected Resources

- IDSA: <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>
- NIH: <https://www.covid19treatmentguidelines.nih.gov/>
- CDC: <https://www.coronavirus.gov>
- WHO: <https://www.who.int/publications/i/item/clinical-management-of-covid-19>
- The Medical Letter:
 - Covid-19 Vaccine Comparison Chart
 - Treatments Considered for COVID-19