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Name of Faculty or Presenter	Reported Financial Relationship
Paul G. Auwaerter, MD, MBA, FIDSA	JNJ: Ownership equity Scientific Consulting: Verily, EMD Serono, Shionogi DMSB: Humanigen

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**COVID19: Keeping Up with a Moving Target** 



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# **Learning Objective**

Describe current NIH recommendations for use of bebtelovimab



This activity is supported by an educational grant from Gilead Sciences, Inc. and in-kind support by DKBmed LLC

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Please see **COVID19.DKBmed.com** for additional resources and educational activities



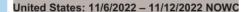
### Paul Auwaerter, MD, MBA, FIDSA

Clinical Director, Division of Infectious Diseases Sherrilyn and Ken Fisher Professor of Medicine Fisher Center for Environmental Infectious Diseases Johns Hopkins University School of Medicine

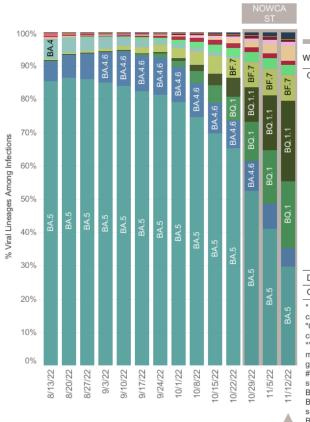


## **US Omicron Subvariants**





USA



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WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.5	VOC	29.7%	27.2-32.3°
	BQ.1.1	VOC	24.1%	21.3-27.39
	BQ.1	VOC	20.1%	17.2-23.4°
	BF.7	VOC	7.8%	6.8-9.0%
	BA.4.6	VOC	5.5%	5.0-6.2%
	BN.1	VOC	4.3%	3.0-6.2%
	BA.5.2.6	VOC	2.9%	2.5-3.4%
	BA.2	VOC	1.3%	0.8-1.9%
	BA.2.75	VOC	1.2%	1.0-1.5%
	BA.2.75.2	VOC	0.9%	0.6-1.2%
	BA.4	VOC	0.1%	0.1-0.1%
	BA.1.1	VOC	0.0%	0.0-0.0%
	B.1.1.529	VOC	0.0%	0.0-0.0%
	BA.2.12.1	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		2.0%	1.1-3.3%

<sup>\*</sup> Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. 
"Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.

BA.5 declining (actual 10/22/22 data) Projection = NOWCAST

BA.4.6, BQ.1, BQ1.1, BF.7 + others

S:R346 mutations

Tixagevimab/cilgavimab
(Evusheld)
&
Bebtelovimab
w/ loss of in vitro activity

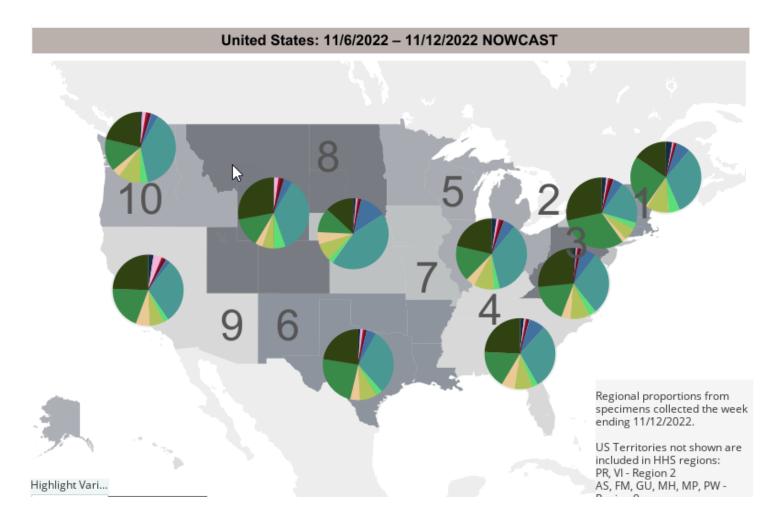
https://covid.cdc.gov/covid-data-tracker/#variant-proportions (accessed 11/15/22)

<sup>\*\*</sup> These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

<sup>#</sup> BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. Except BA.2.12.1, BA.2.75, BA.2.75.2, BN.1 and their sublineages, BA.2 sublineages are aggregated with BA.2. Except BA.4.6, sublineages of BA.4 are aggregated to BA.4. Except BF.7, BA.5.2.6, BQ.1 and BQ.1.1, sublineages of BA.5 are aggregated to BA.5. For all the lineages listed in the above table, their sublineages are aggregated to the listed parental.



# **Some Variability Predicted Regionally**



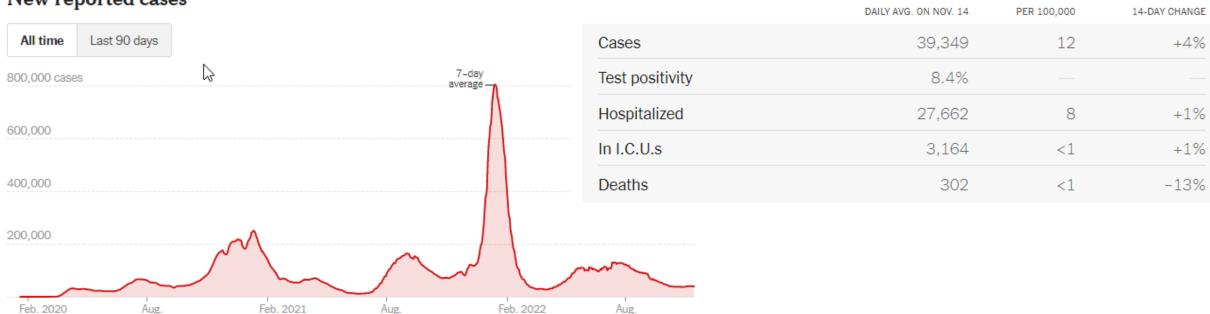


# Will Evolving Subvariants Change Trends?

Deaths

Feb. 2020

### New reported cases



Nov. 2022

NYT/CDC 11/15/22

Test positivity rate

Hospitalized

Feb. 2020

Nov. 2022



# **NIH COVID Treatment Guidelines**

- Despite growing subvariants
  - Continues to recommend Evusheld (BIIb)
    - No alternatives for PrEP
- Bebtelovimab
  - Use for treatment
    - "Only when majority of circulating subvariants in region are susceptible"

https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/Last Updated 11/10/22



# FDA EUA for Anakinra (anti-IL1) mAb

- FDA approved for RA, cryopyrin-associated periodic fever, anti-IL1 def.
- EUA for severe COVID pneumonia requiring oxygen
- RCT SAVE-MORE (n = 594)
  - Used ↑ soluble urokinase plasminogen activator receptor levels to identify study population
  - Dosed 100 mg SQ daily x 10d v. placebo
  - Well tolerated
  - 1° endpoint: WHO-11 pt scale, 28-day odds of more severe disease (OR: 0.37 [95% CI 0.26 to 0.50])
  - No difference in mortality
- Alternative to tocilizumab or baricitinib for severe, progressive COVID-19

https://www.kineretrxhcp.com/pdf/Fact%20Sheet%20for%20Healthcare%20Providers.pdf Kyriazopoulou E, Nature Med 9/3/2021



# **SAVE-MORE** Primary Outcome: Clinical Improvement WHO 11 pt scale

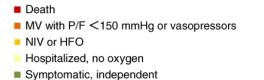


Goodness-of-fit test (Pearson's chi-square test)

P = 0.172

Assumption of proportional odds (test of parallel lines)

P = 0.131



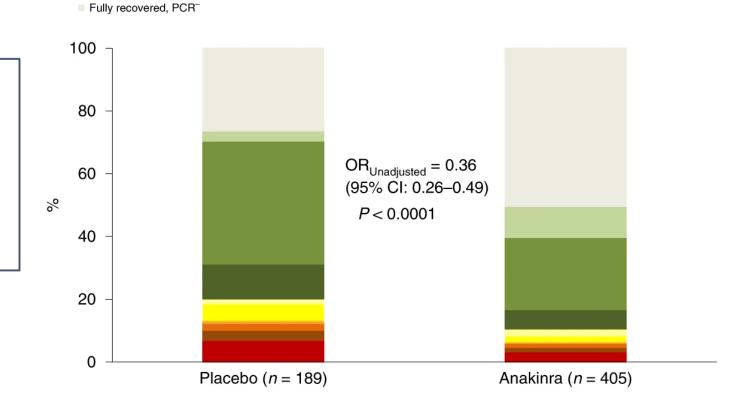
■ MV with P/F <150 mmHg and vasopressors, hemodialysis or ECMO

■ MV with P/F ≥150 mmHg

Hospitalized with oxygen

■ Symptomatic, assistance needed

Asymptomatic, PCR<sup>+</sup>



Kyriazopoulou E, nature med 9/3/2021





What is known now about rebound infections with nirmatrelvir?





The White House advisor said the US is not headed towards another COVID surge this holiday season. Do you agree with this?



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Upon registering and successfully completing the activity evaluation, you will have immediate access to your certificate.

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### To ask your own question, email:

QA@dkbmed.com