

January 10, 2023

Recap and Recharge: COVID-19

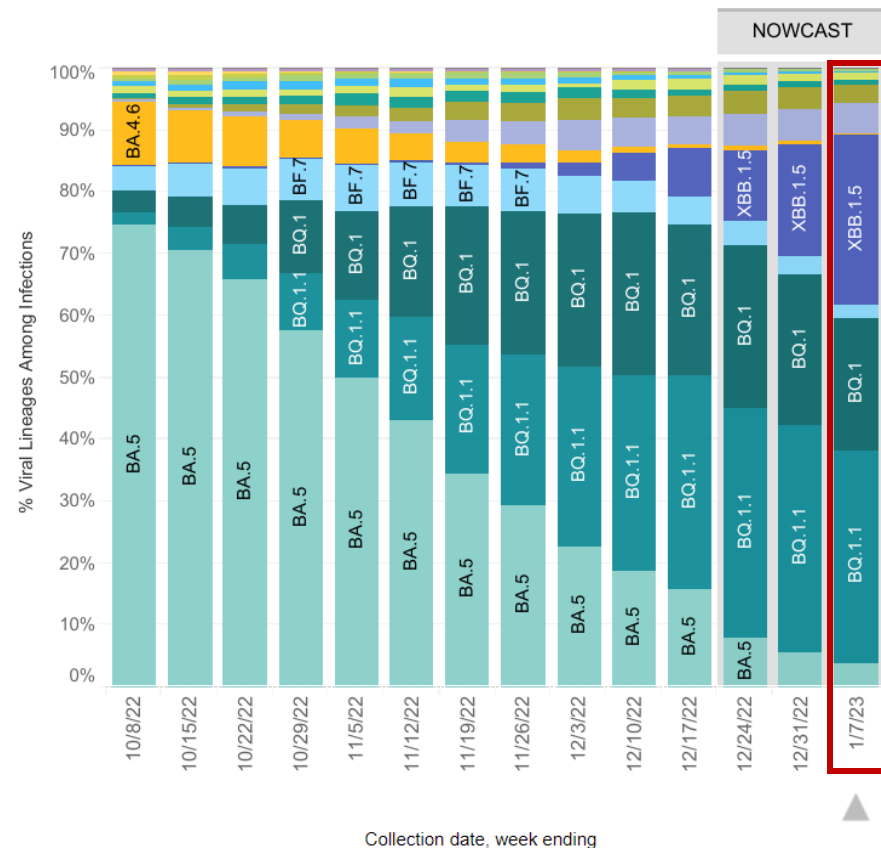
COVID-19 Variants Nationally

United States: 1/1/2023 – 1/7/2023 NOWCAST

United States: 10/2/2022 – 1/7/2023

USA

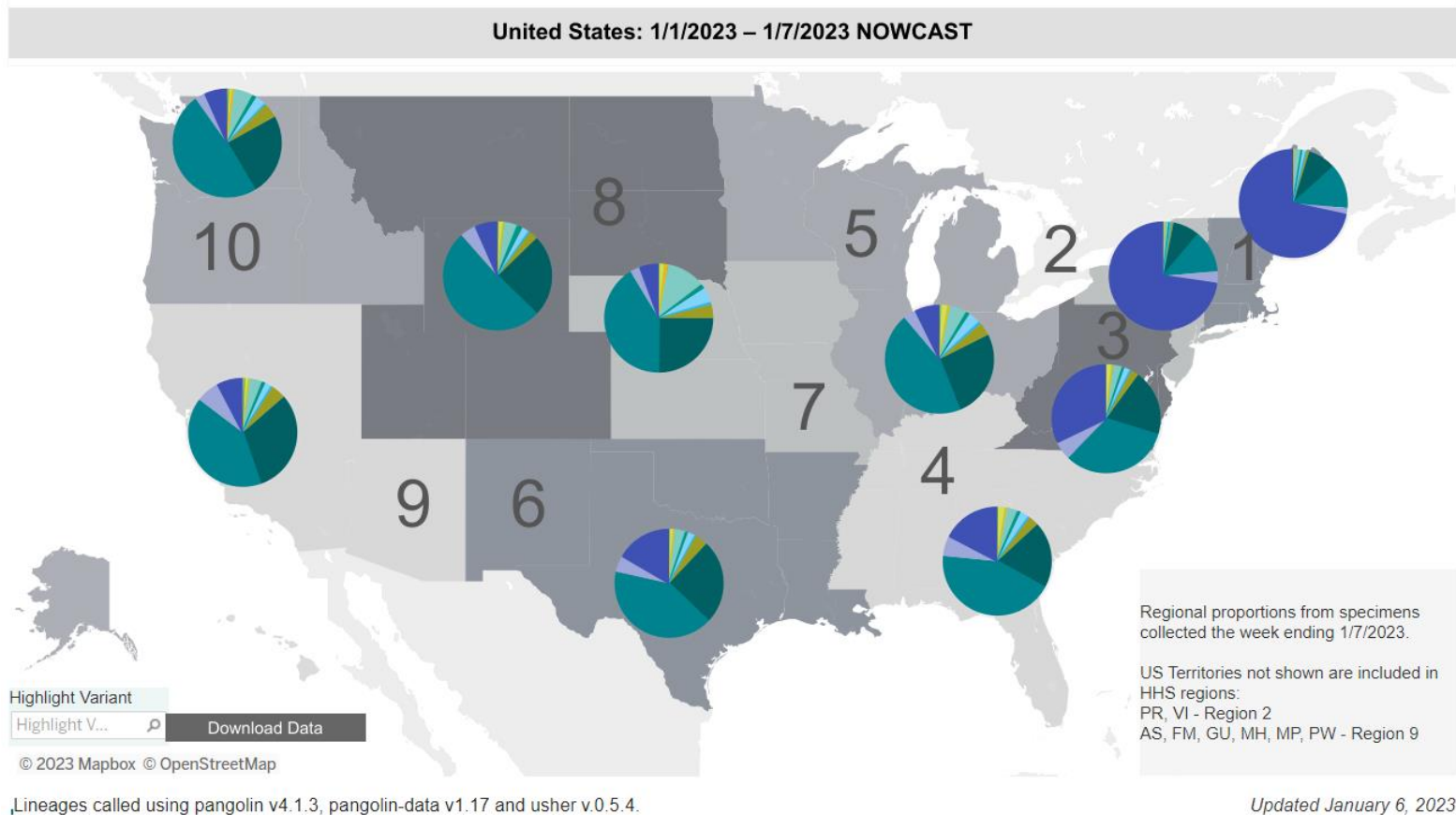
WHO label	Lineage #	US Class	%Total	95%PI	
Omicron	BQ.1.1	VOC	34.4%	26.7-43.0%	
	XBB.1.5	VOC	27.6%	14.0-46.5%	
	BQ.1	VOC	21.4%	16.1-27.7%	
	XBB	VOC	4.9%	4.0-6.1%	
	BA.5	VOC	3.7%	2.7-5.0%	
	BN.1	VOC	3.0%	2.1-4.1%	
	BF.7	VOC	2.2%	1.6-3.0%	
	BA.2.75	VOC	1.3%	0.9-2.0%	
	BA.5.2.6	VOC	0.7%	0.5-0.9%	
	BA.2	VOC	0.3%	0.2-0.5%	
	BF.11	VOC	0.3%	0.2-0.4%	
	BA.4.6	VOC	0.2%	0.2-0.3%	
	BA.2.75.2	VOC	0.1%	0.1-0.1%	
	BA.4	VOC	0.0%	0.0-0.0%	
	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*		0.0%	0.0-0.1%	



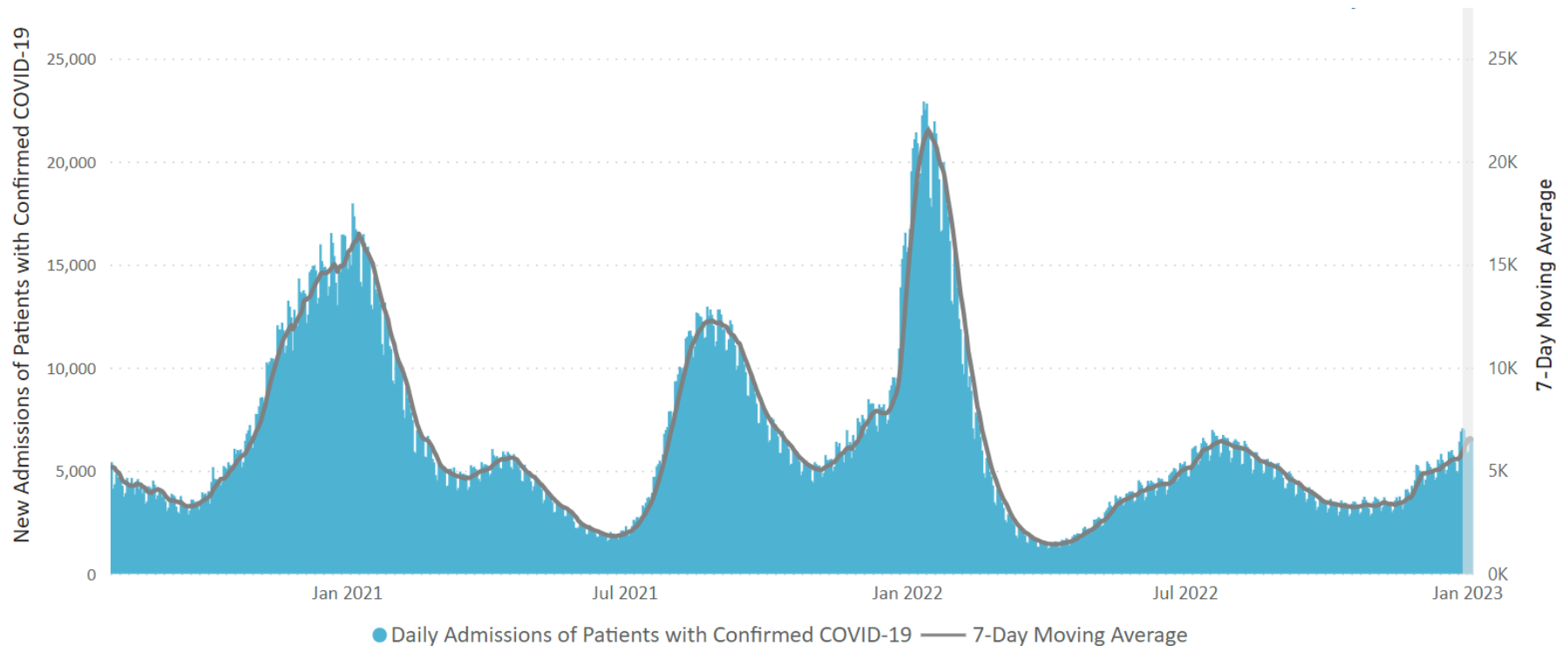
Collection date, week ending



COVID-19 Variants Regionally



Admissions of Patients with Confirmed COVID-19, US



COVID-19 Preventative Agents and Therapeutics

- Inpatient = no changes
- **Outpatient**



Therapeutics activity against emerging variants

Evusheld resistant variants = ~93%

- BQ1.1 = 34.4%
- BQ.1 = 21.4%
- BA.4.6 = 0.2%
- BA.5.2.6 = 0.7%
- BF.7 = 2.2%
- BF.11 = 0.3%
- BA.2.75.2 = 1.3%
- XBB = 4.9%
- XBB.1.5** = 27.6%

**Predicted resistant, confirmatory data on Evusheld loss of activity is pending

Paxlovid/Molnupiravir/Remdesivir

- Expected to retain activity against all circulating variants based on preliminary data & sequence analysis

mAbs currently not authorized for use are routinely tested against emerging variants

- Regen-COV
- Bam/ete
- Sotrovimab
- Bebtelovimab

UW Medicine stopped offering Nov 14



FDA releases important information about risk of COVID-19 due to certain variants not neutralized by Evusheld

Update [1/6/2023] FDA is closely monitoring the emergence of the XBB.1.5 subvariant, a SARS-CoV-2 Omicron variant that is currently estimated to account for 28% of circulating variants in the U.S. Because of its similarity to variants that are not neutralized by Evusheld (e.g., XBB), FDA does not anticipate that Evusheld will neutralize XBB.1.5. This means that Evusheld may not provide protection against developing COVID-19 for individuals who have received Evusheld and are later exposed to XBB.1.5. However, we are awaiting additional data to verify that Evusheld is not active against XBB.1.5. We will provide further updates as new information becomes available.

Health care providers should inform individuals of the increased risk, compared to other variants, for COVID-19 due to SARS-CoV-2 variants not neutralized by Evusheld.

If signs and symptoms of COVID-19 occur, advise individuals to test for COVID-19 and seek medical attention, including starting treatment for COVID-19 as appropriate.



NIH Summary of Outpatient COVID-19 Preventative Agents & Treatments

No Illness

**Baseline health status, no
infection**

COVID-19 Vaccines

Monoclonal antibody for PrEP

Evusheld (tixagevimab +
cilgavimab)

"Breakthrough infections are possible,
advise patients to have a treatment plan in
place and seek timely medical attention if
symptoms occur"



Vaccine Updates

Updated (bivalent) boosters became available on:	September 2, 2022, for people aged 12 years and older
	October 12, 2022, for people aged 5–11 years
	December 9, 2022, for children aged 6 months–4 years who completed the Moderna COVID-19 vaccine primary series
No booster recommendation for children aged 6 months–4 years who got the Pfizer-BioNTech COVID-19 vaccine primary series	December 9, 2022, updated (bivalent) Pfizer-BioNTech COVID-19 vaccine also became available for children aged 6 months–4 years to complete the primary series

Find Out When You Can Get Your Booster



Boosters are an important part of protecting yourself or your child from getting seriously ill or dying from COVID-19. People ages 6 months and older should receive one updated (bivalent) booster, if they are eligible, including those who are moderately or severely immunocompromised.

[Find Out When to Get a Booster >](#)

People who did not receive Pfizer-BioNTech, Moderna, Novavax, or Johnson & Johnson's Janssen, like [people who were vaccinated abroad](#), have specific recommendations.










This tool is intended to help you make decisions about getting COVID-19 vaccinations. It should not be used to diagnose or treat COVID-19.



**GREAT tool on
CDC website**



Covid-19 Vaccine Comparison Chart (Primary Series)

Manufacturer	Pfizer ^c	Pfizer ^c	Pfizer ^c	Pfizer ^c	Moderna	Moderna	Moderna	Janssen	Novavax
Formulation	Monovalent	Bivalent	Monovalent	Monovalent	Monovalent	Monovalent	Monovalent	Monovalent	Monovalent
Age group	6mo-4yr	6mo-4yr	5-11yr	≥12yr	6mo-5yr	6yr-11yr	≥12yr	≥18yr	≥12yr
Vial image									
1 st Primary Dose	3 mcg/0.2 mL	NA	10 mcg/0.2 mL	30 mcg/0.3 mL	25 mcg/0.25 mL	50 mcg/0.5 mL	100 mcg/0.5 mL	0.5 mL	0.5 mL
2 nd Primary Dose	3 mcg/0.2 mL	NA	10 mcg/0.2 mL	30 mcg/0.3 mL	25 mcg/0.25 mL	50 mcg/0.5 mL	100 mcg/0.5 mL	NA	0.5 mL
3 rd Primary Dose	NA	(1.5mcg+1.5mcg)/0.2 mL	10 mcg/0.2 mL ^b	30 mcg/0.3 mL ^b	25 mcg/0.25 mL ^b	50 mcg/0.5 mL ^b	100 mcg/0.5 mL ^b	NA	NA
Diluent per vial	2.2 mL*	2.2 mL*	1.3 mL*	No Dilution	No Dilution	No Dilution	No Dilution	No Dilution	No Dilution
Doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)	10 doses per vial (after dilution)	6 doses per vial	10 doses of 0.25mL per vial	5 doses of 0.5mL per vial	10 doses of 0.5mL per vial	5 doses per vial	10 doses of 0.5mL per vial
Protect from light during storage	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ultra-Low-Temp (ULT) Freezer [-90C to -60C]	18 months [†]	18 months [†]	18 months [†]	18 months [†]	Do Not Store	Do Not Store	Do Not Store	Do Not Store	Do Not Store
Freezer [-50C to -15C]	Do Not Store	Do Not Store	Do Not Store	Do Not Store	Until expiration date ^x	Until expiration date ^x	Until expiration date ^x	Do Not Store	Do Not Store
Refrigerator (unpunctured) [2C to 8C]	70 days	70 days	70 days	70 days	30 days	30 days	30 days	Until expiration date [§]	Until expiration date [‡]
Room Temp (RT) (unpunctured) [8C to 25C]	12 hours (including any thaw time)	12 hours (including any thaw time)	12 hours (including any thaw time)	12 hours (including any thaw time)	24 hours	24 hours	24 hours	12 hours	Do Not Store
After First Puncture	Discard after 12 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard after: • 6 hours refrigerated • 2 hours at RT	Discard after 6 hours (RT or refrigerated)

^aThose moderately to severely immunocompromised that completed an initial 2-dose vaccine series of Pfizer-BioNTech or Moderna or received 1 dose of Janssen.

^cPfizer vaccine info excerpted from <https://www.cvdvaccine-us.com/>

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Bacteriostatic saline or other diluents must NOT be used.

[†]Regardless of storage condition, vaccines should not be used after 18 months from the date of manufacture printed on the vial and cartons.



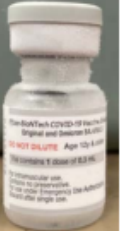

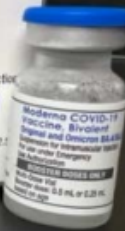


^xConfirm Moderna vaccine manufacturer expiration date by looking up lot number at <https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup?#vialLookupTool>.

[§]Confirm Janssen vaccine manufacturer expiration date by looking up lot number at <https://vaxcheck.inj/>

[‡]Confirm Novavax vaccine manufacturer expiration date by looking up lot number at <https://us.novavaxcovidvaccine.com/hcp>



Covid-19 Vaccine Comparison Chart (Booster)

Manufacturer	Pfizer ^c	Pfizer ^c Multiple Dose Vial	Pfizer ^c Single Dose Vial	Moderna	Moderna	Janssen	Novavax
Formulation	Bivalent	Bivalent	Bivalent	Bivalent	Bivalent	Monovalent	Monovalent
Age group	5yr-11yr	≥12yr	≥12yr	6mo-5yr	≥6yr	≥18yr	≥18yr
Vial image							
Booster Dose	(5 mcg + 5mcg) /0.2 mL	(15 mcg + 15 mcg) /0.3 mL	(15 mcg + 15 mcg) /0.3 mL	(5 mcg + 5 mcg) /0.2 mL	6-11yr booster dose: (12.5 mcg + 12.5 mcg) /0.25 mL ≥12yr booster dose: (25 mcg + 25 mcg) /0.5 mL	0.5 mL	0.5 mL
Diluent per vial	1.3 mL*	No Dilution	No Dilution	No Dilution	No Dilution	No Dilution	No Dilution
Doses per vial	10 doses per vial (after dilution)	6 doses per vial	1 dose per vial	2 doses per vial	5 doses of 0.5mL per vial	5 doses per vial	10 doses of 0.5mL per vial
Protect from light during storage	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ultra-Low-Temp (ULT) Freezer [-90C to -60C]	18 months [†]	18 months [†]	18 months [†]	Do Not Store	Do Not Store	Do Not Store	Do Not Store
Freezer [-50C to -15C]	Do Not Store	Do Not Store	Do Not Store	Until expiration date [‡]	Until expiration date [‡]	Do Not Store	Do Not Store
Refrigerator (unpunctured) [2C to 8C]	70 days	70 days	70 days	30 days	30 days	Until expiration date [§]	Until expiration date [§]
Room Temp (RT) (unpunctured) [8C to 25C]	12 hours (including any thaw time)	12 hours (including any thaw time)	12 hours (including any thaw time)	24 hours	24 hours	12 hours	Do Not Store
After First Puncture	Discard after 12 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard immediately	Discard after 8 hours (RT or refrigerated)	Discard after 12 hours (RT or refrigerated)	Discard after: • 6 hours refrigerated • 2 hours at RT	Discard after 6 hours (RT or refrigerated)

^cPfizer vaccine info excerpted from <https://www.cvdvaccine-us.com/>

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Bacteriostatic saline or other diluents must NOT be used.

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NIH Summary of Outpatient COVID-19 Preventative Agents & Treatments

No Illness

Baseline health status, no infection

COVID-19 Vaccines

Monoclonal antibody for PrEP

Evusheld (tixagevimab + cilgavimab)

Exposed

Not hospitalized

None currently authorized

Mild to Moderate Symptoms

Not hospitalized for COVID-19

Preferred

Paxlovid (nirmatrelvir + ritonavir)

Veklury (remdesivir)

Alternative

Lagevrio (Molnupiravir)

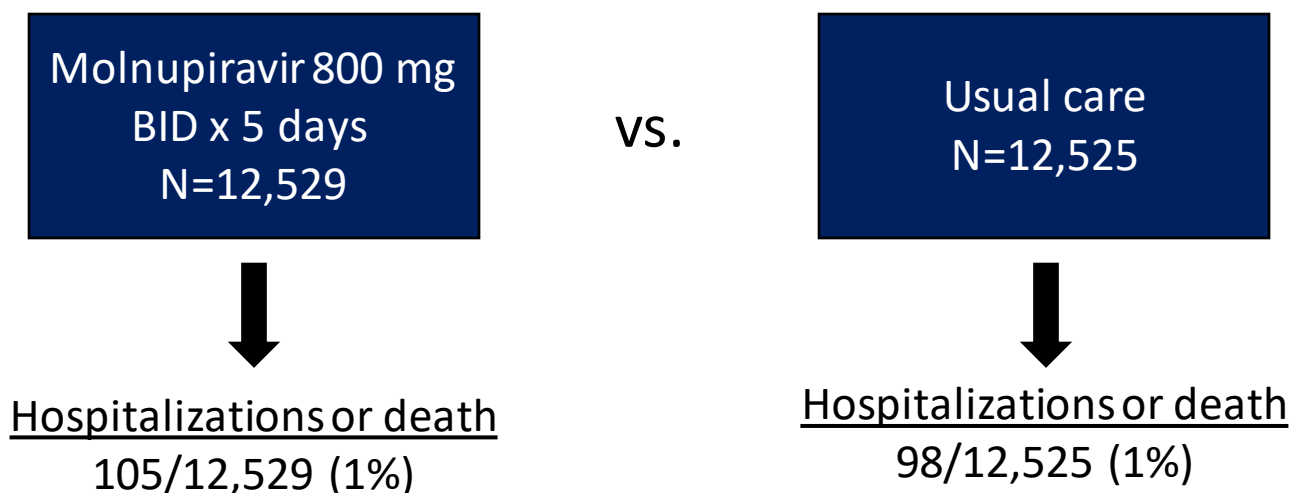
"Breakthrough infections are possible, advise patients to have a treatment plan in place and seek timely medical attention if symptoms occur"



Molnupiravir plus usual care versus usual care alone as early treatment for adults with COVID-19 at increased risk of adverse outcomes (PANORAMIC): an open-label, platform-adaptive randomised controlled trial

Published Dec 22, 2022

Study population: age >50 years, highly vaccinated at high risk (94% of population had at least three doses of SARS-CoV-2 vaccine), and infected with Omicron



Adjusted odds ratio 1.06 [95% BCI 0.81-1.14]

Conclusion: Molnupiravir did not reduce the frequency of COVID-19-associated hospitalizations or death among high-risk vaccinated adults in the community

VV116 versus Nirmatrelvir–Ritonavir for Oral Treatment of Covid-19

Z. Cao, W. Gao, H. Bao, H. Feng, S. Mei, P. Chen, Yueqiu Gao, Z. Cui, Q. Zhang,

Published Dec 28, 2022

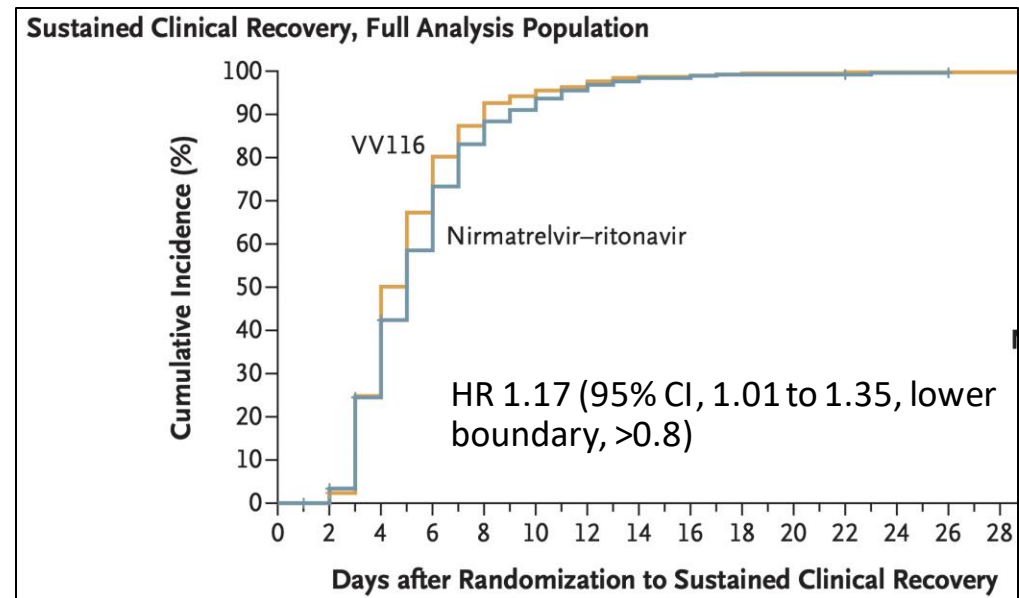
Multicenter, observer-blinded, randomized, controlled trial

Oral VV116
(600 mg every 12 hours on day 1 and 300 mg every 12 hours on days 2 through 5)
N=367

vs.

Oral nirmatrelvir–ritonavir
(300 mg of nirmatrelvir plus 100 mg of ritonavir every 12 hours for 5 days)
N=375

- VV116 = oral analogue of remdesivir
- Study population:
 - Median age 53 years
 - Mainly vaccinated (76% of population were fully vaccinated or boosted)
 - Infected with Omicron (mainly BA.2.2)
- Primary endpoint: time to sustained clinical recovery through day 28



Non-inferior



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N=367

vs.

Oral nirmatrelvir–ritonavir
(300 mg of nirmatrelvir plus 100 mg of ritonavir every 12 hours for 5 days)
N=375

Secondary end points	VV116	Pax
Progression to severe Covid-19 or death by day 28 — no. (%)	0	0

- Possible efficacy for this outcome is planned to be evaluated in a separate trial (ClinicalTrials.gov number, NCT05242042).

Conclusion: oral VV116 was noninferior to pax in **shortening the time to sustained clinical recovery** in participants with mild-to-moderate Covid-19 who were at high risk for progression to severe disease. VV116 also had **fewer safety concerns** than pax.



How can you order remdesivir?

Hospital ordering process

Hospitals can place orders with any of the following distributors by calling directly:

- **AmerisourceBergen Specialty Distribution**, 1-800-746-6273
- **Cardinal Specialty**, 1-855-855-0708
- **McKesson Plasma**, 1-877-625-2566

Nonhospital ordering process

Non-hospitals can contact AmerisourceBergen Specialty Distribution or Cardinal Specialty:

AmerisourceBergen Specialty: (t) 1-800-746-6273 (e) C19therapies@AmerisourceBergen.com

Cardinal Specialty: (t) 1-855-855-0708 (e) GMB-SPD-CSORDERENTRY@cardinalhealth.com



Supplier

Gilead sells VEKLURY
to Specialty Distributor



Ordering

Approved classes of
trade can place orders
with specialty distributor



Shipment

Specialty distributor
ships VEKLURY directly
to hospital/nonhospital
customer



Eligibility requirements for remdesivir

These entities can purchase from their respective distributors:

- Hospitals (ASD, CAH & MPB);
- Non-hospital entities include (ASD & CAH only):
 - Infusion centers or sites;
 - Long term care sites;
 - Skilled nursing facilities
 - Dialysis care;
 - Clinics; and
 - Acute/urgent care

These entities will require attestation from ASD and/or CAH to purchase to ensure appropriate use:

- Retail pharmacies and specialty pharmacies must attest via the Distributor process for
 - Long-term care sites
 - Skilled Nursing facilities

ASD = Amerisource Bergen Specialty Distribution
CAH = Cardinal Health Specialty Distribution
MPB = McKesson Plasma and Specialty Distribution



How to help patients afford remdesivir

Advancing Access Program Offerings to Assist Patients Prescribed VEKLURY



Advancing Access® is here to help patients starting on a prescribed Gilead medication

Advancing Access program specialists can provide coverage information and financial support options for eligible patients



General Inquiries

Questions about the Advancing Access program or about coverage for a patient's prescribed VEKLURY



Insurance Verification & Prior Authorization/Appeals Process Information - Outpatient Setting Only

Support with insurance verification to determine a patient's coverage through their insurance plan. Support with Prior Authorization and/or appeals process information, if needed



Co-Pay Coupon Program - Outpatient Setting Only

Co-pay coupon program for commercially insured, eligible patients



Patient Assistance Program (PAP) - Outpatient Setting Only

Free product support for uninsured/under-insured eligible patients

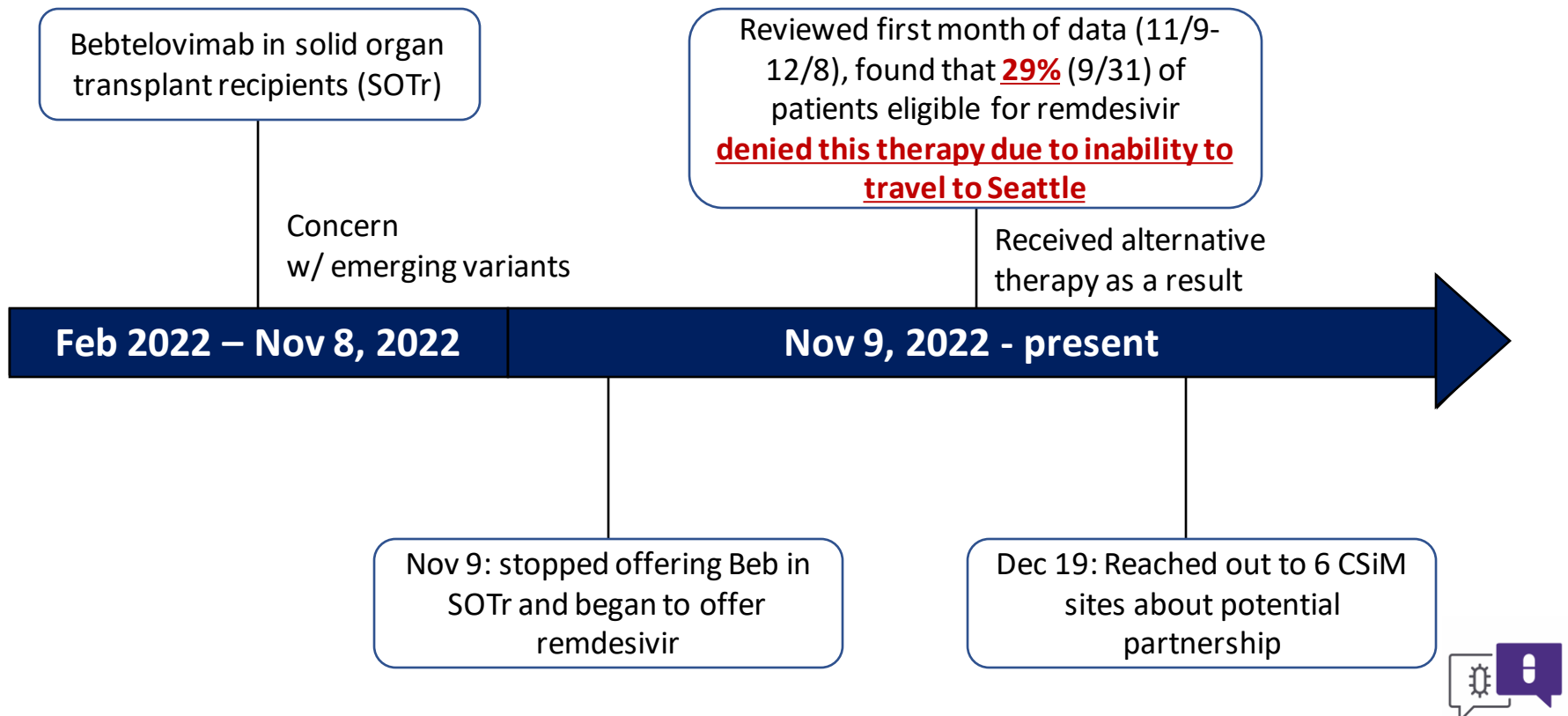


CSiM ftw



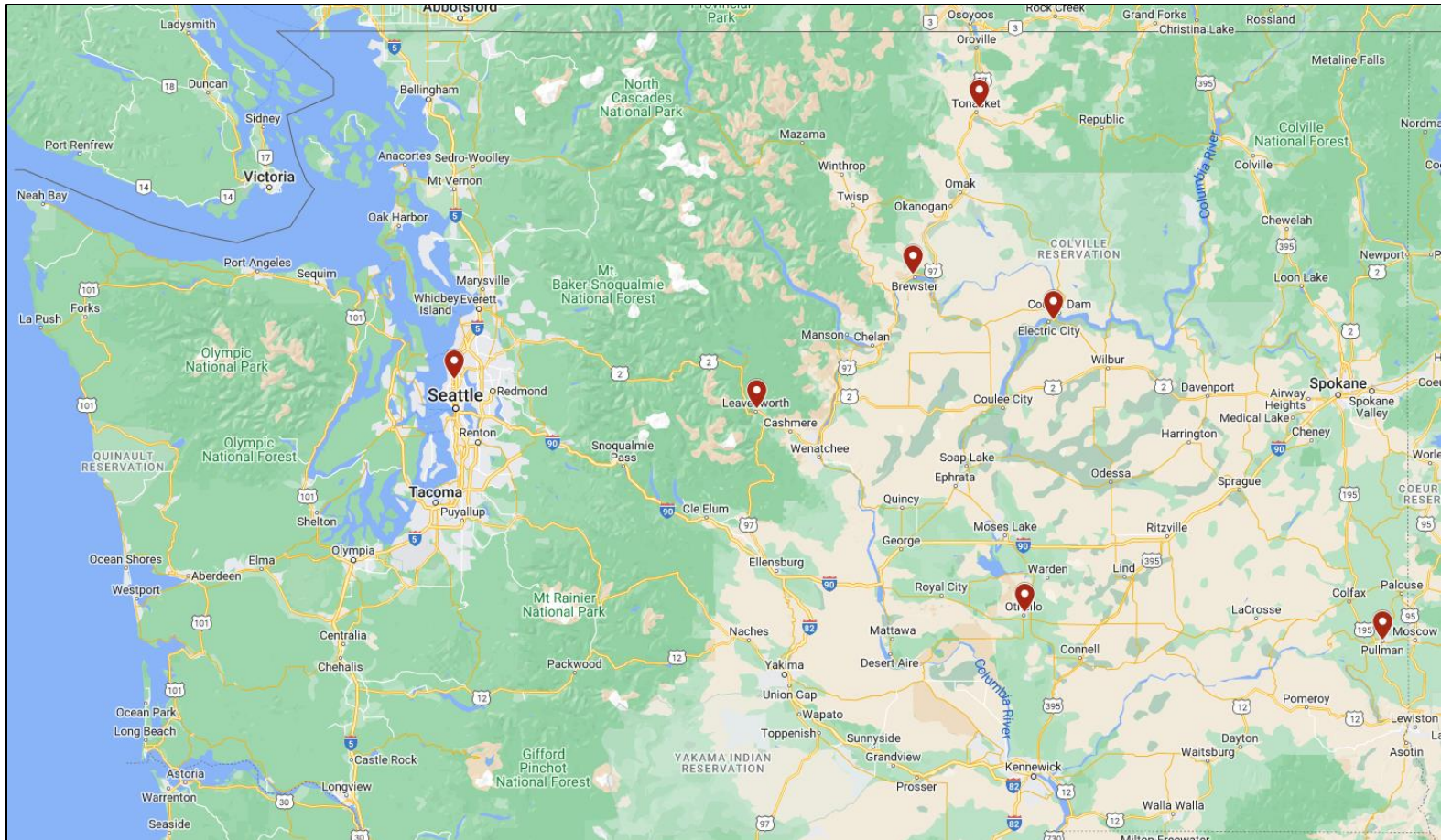
Background

- UW Medicine offers numerous transplant services
 - Patients come from all over the Northwest for specialty care



Because of CSiM...

Identify SIX additional partners across WA



Able to expand remdesivir access



Thank you!!

- Cascade Medical (Leavenworth)
- Coulee Medical Center (Grand Coulee)
- North Valley Hospital (Tonasket)
- Othello Community Hospital (Othello)
- Pullman Regional Hospital (Pullman)
- Three Rivers Hospital (Brewster)

