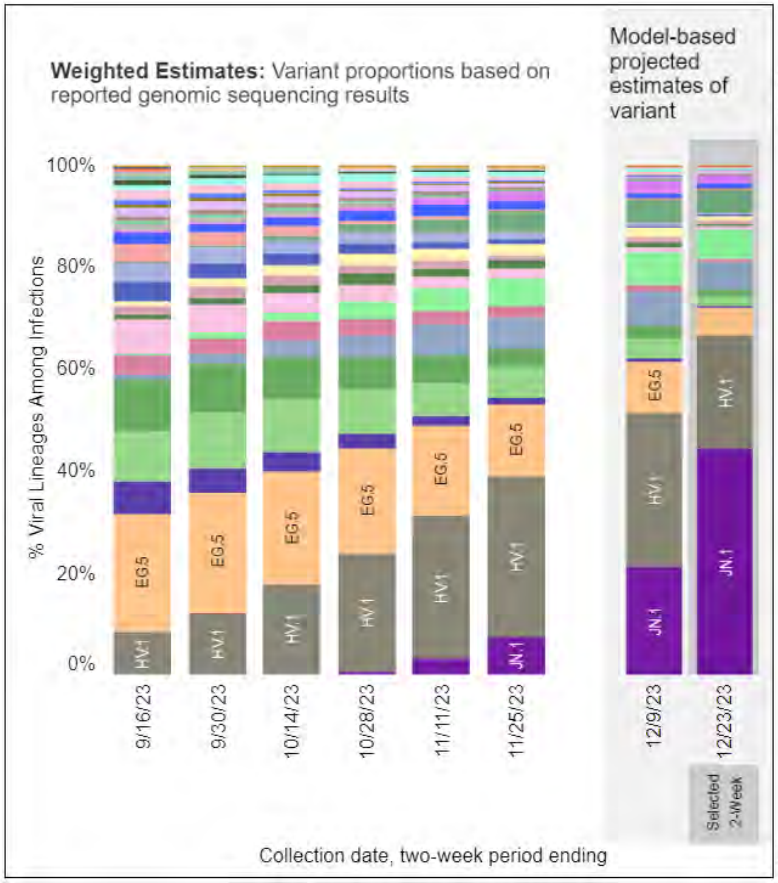
VDH VIRGINIA DEPARTMENT OF HEALTH

COVID-19 Variants, Subvariants, Drug Activity, and Information

Updated December 28, 2023 5 PM

CDC Nowcast as of December 23, 2023 – Nationwide Data Estimates



USA

WHO label	Lineage #	%Total	95%PI
Omicron	JN.1	44.2%	38.8-49.7%
	HV.1	22.1%	19.9-24.5%
	JD.1.1	5.6%	4.6-6.9%
	HK.3	5.5%	4.9-6.2%
	EG.5	5.5%	4.7-6.3%
	JG.3	4.8%	4.0-5.8%
	BA.2.86	2.0%	1.5-2.7%
	FL.1.5.1	1.9%	1.6-2.3%
	JF.1	1.4%	1.1-1.8%
	XBB.1.16.6	1.2%	0.9-1.5%
	XBB.1.9.1	0.7%	0.5-1.0%
	XBB.1.16.11	0.7%	0.5-1.0%
	XBB.2.3	0.6%	0.5-0.8%
	GK.1.1	0.6%	0.4-0.7%
	XBB.1.16	0.5%	0.3-1.0%
	XBB.1.5.70	0.5%	0.4-0.8%
	HF.1	0.5%	0.3-0.7%
	XBB.1.16.15	0.3%	0.2-0.5%
	BA.2	0.3%	0.0-2.1%
	XBB	0.3%	0.2-0.3%
	GE.1	0.2%	0.1-0.3%
	GK.2	0.1%	0.1-0.2%
	CH.1.1	0.1%	0.0-0.1%
	EG.6.1	0.1%	0.1-0.1%
	XBB.1.5	0.1%	0.0-0.1%
	XBB.1.16.1	0.1%	0.0-0.1%
	XBB.1.42.2	0.0%	0.0-0.1%
	XBB.1.5.68	0.0%	0.0-0.0%
	XBB.2.3.8	0.0%	0.0-0.1%
	XBB.1.9.2	0.0%	0.0-0.0%
	XBB.1.5.72	0.0%	0.0-0.0%
	XBB.1.5.10	0.0%	0.0-0.0%
	XBB.1.5.59	0.0%	0.0-0.0%
	FD.1.1	0.0%	0.0-0.0%
Other	Other*	0.0%	0.0-0.1%

Drug Activity Against SARS-CoV-2 Variants and Subvariants – as of 12/23/2023

	Omicron JN.1	Omicron HV.1	Omicron JD.1.1	Omicron HK.3	Omicron EG.5	Omicron JG.3	Omicron BA.2.86	Omicron FL.1.5.1
EVUSHELD (mAb for PrEP, given intramuscularly)	Evusheld Emergency Use Authorization (EUA) amended by FDA on Jan 26, 2023. Evusheld only authorized for use when the combined frequency of non-susceptible variants nationally is less than or equal to 90%. **Evusheld is NOT currently authorized for use in any U.S. Region.**							
Bebtelovimab (mAb for Covid-19 treatment, given IV)	Due to the high frequency of variants/subvariants that are resistant to it, as of Nov 30, 2022, Bebtelovimab is NOT authorized for use in any U.S. Region.							
Paxlovid (nirmatrelvir with ritonavir) (oral Covid-19 antiviral)	Active	Active	Active	Active	Active	Active	Active	Active
Lagevrio (molnupiravir) (oral Covid-19 antiviral)	Active	Active	Active	Active	Active	Active	Active	Active
Veklury (remdesivir) (IV Covid-19 antiviral)	Active	Active	Active	Active	Active	Active	Active	Active

Key:

- Active = drug is currently active or believed to be active against this variant/subvariant
- Not likely to be active = based on testing, drug is not likely to be active against this variant/subvariant
- Not active = based on testing, drug is **inactive** against this variant/subvariant
- No data = no current testing has been reported about this drug against this variant/subvariant

Recent Developments / Talking Points:

- Mutations of the SARS-CoV-2 virus are an expected occurrence and have taken place since the virus was originally discovered (e.g., Alpha, Beta, Delta, Omicron variants).
- On December 20, 2023, the National Institutes of Health COVID-19 Treatment Guidelines Panel (the Panel) updated the Guidelines as follows:
  - Regarding the future of the guidelines, the last update will be published in early 2024. The Guidelines will remain available for several months and then a downloadable version of the final report will be available.
  - Fluvoxamine: Clinical trials have been done to see if fluvoxamine, a selective serotonin reuptake inhibitor (SSRI) that is FDA approved for the treatment of obsessive-compulsive disorder, is effective for the treatment of nonhospitalized patients with COVID-19. Multiple trials did not show a benefit of using fluvoxamine for the treatment of acute COVID-19 in nonhospitalized patients. As a result, the Treatment Guidelines Panel recommends against the use of fluvoxamine for the treatment of COVID-19 in nonhospitalized patients.
  - Vitamin C: Vitamin C (ascorbic acid) is a water-soluble vitamin that is an antioxidant and has anti-inflammatory properties. In an open-label clinical trial conducted at two sites in the U.S., outpatients with COVID-19 were randomized to receive high-doses of daily Vitamin C (8,000 mg), zinc gluconate (50 mg), both agents, or usual standard of care. The primary end point was the number of days needed to achieve a 50% reduction in symptoms. This trial was stopped early because of lack of benefit after only 214 (of a proposed 520) subjects had been randomized. The Treatment Guidelines Panel noted there is insufficient evidence to recommend either for or against the use of Vitamin C for the treatment of COVID-19 in nonhospitalized patients.
- On December 6, 2023, NIH announced an expansion of the Home Test to Treat program, an entirely virtual community health program that offers free COVID-19 health services for **adults**: at-home rapid tests, telehealth sessions and at-home treatments, to eligible participants nationwide. The Home Test to Treat program will now offer free testing, telehealth, and treatment for COVID-19 and for influenza (flu) A and B. For more information about Home Test to Treat or to use the program, go to this website.
- Currently, non-U.S. Government organizations can only obtain the oral COVID-19 antiviral drugs Paxlovid (nirmatrelvir with ritonavir) and Lagevrio (molnupiravir) through the commercial marketplace. Regarding Paxlovid, as of December 15, 2023, only U.S. Government (USG) agencies can continue to order this medication from the USG supply at no cost.
- As of 12/23/2023, major Omicron variants/subvariants in HHS Region 3 (includes VA, DE, Washington D.C., MD, PA, WV) include:
  - JN.1 estimated prevalence 38.9%
  - HV.1 estimated prevalence 25.6%
  - JD.1.1 estimated prevalence 7.5%
  - EG.5 estimated prevalence 5.2%
  - HK.3 estimated prevalence 5.0%
  - JG.3 estimated prevalence 4.9%
  - BA.2.86 estimated prevalence 3.0%
  - FL.1.5.1 estimated prevalence 2.3%

- Nationwide, according to the CDC Nowcast dated 12/23/2023, there are 10 Omicron variants/subvariants each with an estimated prevalence of ≥1%. There are also 16 Omicron variants/subvariants each with an estimated prevalence <1%.
- The three current antiviral drugs (nirmatrelvir with ritonavir [Paxlovid], remdesivir [Veklury], and molnupiravir [Lagevrio]) are expected to have activity against all current circulating variants
- According to its EUA, molnupiravir is a treatment option only if Paxlovid or remdesivir are not appropriate medications for a patient or they are not available.
- Prescribers are advised to monitor variant frequency in their area and refer to FDA fact sheets to see if a specific drug is expected to be active against specific variants/subvariants.
- Oral Paxlovid continues to be NIH's first-choice drug and IV remdesivir the next preferred option for treatment of mild to moderate COVID-19 in high-risk outpatients. See the NIH Treatment Panel's section on Antiviral Agents, including Antibody Products.
- Currently, Paxlovid is FDA approved (prescribing information) for adults ≥ 18 years with mild to moderate COVID-19 who are at high-risk for progression to severe disease. Paxlovid remains under Emergency Use Authorization (EUA) for children ages 12 through 17. Lagevrio remains under an EUA.
- **Immunocompromised patients**: Currently, Evusheld is not authorized for use in any U.S. Region. Therefore, patients with moderate to severe immunocompromise should have a plan of action in place if they become ill with COVID-19-like symptoms. They are advised to: 1) have a supply of home COVID-19 tests available, 2) test themselves right away, 3) contact their medical provider promptly with the result of the COVID-19 test, 4) have a mechanism in place to obtain Paxlovid promptly if the patient's healthcare provider prescribes it, and 5) if the patient is unable to take oral Paxlovid, talk with their medical provider about using an alternate drug such as remdesivir, Lagevrio, or COVID-19 convalescent plasma for treatment.
    - To be eligible for treatment with Paxlovid or Lagevrio, patients must start the medication within 5 days of COVID-19 symptom onset. With remdesivir (Veklury), the drug must be started within 7 days of symptom onset.
    - **Patients should be treated as early as possible. Patients with mild symptoms who meet EUA criteria should receive treatment**.
- "Legacy" monoclonal antibodies (Bamlanivimab/Etesevimab ["Bam/Ete"], REGEN-COV [casirivimab plus imdevimab], sotrovimab, Bebtelovimab), do NOT have an EUA for any current use including treatment of COVID-19 or postexposure prophylaxis. These drugs are not active against newer Omicron variants.

Treatment and Testing Resources

- Home Test to Treat Program – free at-home COVID-19 and flu diagnostic and treatment services for adults via telehealth
- COVID-19 Test to Treat Locator - helps people quickly access treatment for COVID-19 at little to no cost
- Free COVID-19 tests from federal government – sent via U.S. Mail – 8 free tests per household.
- No-Cost COVID-19 Testing

Sources:

- CDC COVID Data Tracker
- National Institutes of Health (NIH)
    - NIH COVID-19 Treatment Guidelines. What's New in the Guidelines. Updated 12/20/2023.
    - NIH COVID-19 Treatment Guidelines. Therapeutic Management of Nonhospitalized Adults with COVID-19.
- Paxlovid
    - FDA. Approved package insert (May 2023)
    - FDA. Emergency Use Authorization Fact Sheet for Healthcare Providers (revised 11/2023)
- Lagevrio
    - FDA. Emergency Use Authorization Fact Sheet for Healthcare Providers (revised 10/2023)