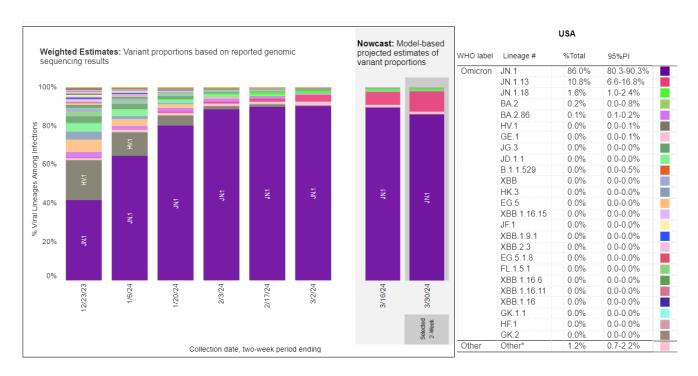


COVID-19 Variants, Subvariants, Drug Activity, and Information

Updated April 8, 2024 3 PM

CDC Nowcast as of March 30, 2024 - Nationwide Data Estimates



Drug Activity Against SARS-CoV-2 Variants and Subvariants – as of 4/5/2024

	Omicron JN.1	Omicron JN.1.13	Omicron JN.1.18	Omicron BA.2	Omicron BA.2.86	Omicron HV.1	Omicron GE.1	Omicron JG.3
Pemgarda								
(mAb for PrEP, given intravenously)	Active	Active	Active	Active	Active	Active	Active	Active
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

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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 March 22, 2024, the FDA granted Emergency Use Authorization (EUA) to the monoclonal antibody pemivibart (brand name Pemgarda) for pre-exposure prophylaxis against COVID-19 in people who:
 - o Are aged ≥ 12 years and who weigh at least 40 kg (about 88 lbs.), and
 - o Are not currently infected with the SARS-CoV-2 virus, and
 - o Have not had a recent exposure with an individual infected with the SARS-CoV-2 virus, and
 - o Have moderate to severe immunocompromise due to a medical condition or medications, and
 - Are not likely to mount an adequate immune response to COVID-19 vaccination
- Items of note regarding Pemgarda:
 - o Pemgarda carries a **boxed warning** about the possibility of anaphylaxis with its use
 - o In a clinical trial, anaphylaxis was observed in 0.6% (4/623) of participants in a clinical trial.
 - Anaphylaxis can be life-threatening. Before administering Pemgarda, the potential benefit of COVID-19 prevention needs to be weighed against the risk of anaphylaxis.
 - o Pemgarda is administered by intravenous (IV) infusion. Patients must be monitored during the infusion and for at least 2 hours post infusion.
 - Pemgarda must be administered in a setting where healthcare providers have access to medications to treat anaphylaxis and the ability to activate the emergency medical system (EMS), as needed.
 - o If symptoms or signs of anaphylaxis develop, Pemgarda infusion should be stopped immediately and appropriate treatment should be given.
 - Pemgarda is a long-acting monoclonal antibody. Repeat dosing can be given in 3 months if the patient continues to meet criteria for Pemgarda use.
 - Be sure to consult the Pemgarda EUA Fact Sheet prior to product use.
- On February 29, 2024, the National Institutes of Health COVID-19 Treatment Guidelines Panel (the Panel) released the <u>final version</u> of the Guidelines. The Treatment Guidelines website will remain available until August 16, 2024, and then a downloadable PDF of the final version will be available.
- The Home Test to Treat Program, an entirely virtual community health program that offers free COVID-19 and influenza telehealth services for adults, will end on April 16, 2024. This program was a nationwide pilot and scheduled to end this month. Through April 16, the program is active.
- As of 3/30/2024, no Omicron variant/subvariant data is available for HHS Region 3 (includes VA, DE, Washington D.C., MD, PA, WV)
- 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.
- 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 <u>FDA approved</u> (<u>prescribing information</u>) for adults ≥ 18 years with mild to
 moderate COVID-19 who are at high-risk for progression to severe disease. Paxlovid remains under
 <u>Emergency Use Authorization</u> (EUA) for children ages 12 through 17. Lagevrio remains under an EUA.
 - To be eligible for treatment with Paxlovid or Lagevrio, patients must start the medication within 5 days of 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.

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• "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
- <u>COVID-19 Test to Treat Locator</u> helps people quickly access treatment for COVID-19 at lower to no cost.
- No-Cost COVID-19 Testing

Sources:

- CDC COVID Data Tracker
- National Institutes of Health (NIH)
 - o NIH COVID-19 Treatment Guidelines. What's New in the Guidelines. Updated 2/29/2024.
 - NIH COVID-19 Treatment Guidelines. <u>Therapeutic Management of Nonhospitalized Adults with COVID-19</u>. Updated 2/29/2024.
- Paxlovid
 - o FDA approved package insert (5/2023)
 - o FDA. Emergency Use Authorization Fact Sheet for Healthcare Providers (revised 3/2024)
- Veklury
 - FDA approved package insert (Updated 2/2024)
- Lagevrio
 - o FDA. Emergency Use Authorization Fact Sheet for Healthcare Providers (revised 10/2023)

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