

Information Sheet - Lagevrio Eligibility and Effectiveness

- **Lagevrio (molnupiravir)** is an antiviral option for the treatment of mild-to-moderate COVID-19 in eligible adult patients with positive results of SARS-CoV-2 testing, at high risk for progression to severe COVID-19, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.
- While vaccination continues to provide the best protection against COVID-19, therapies are now widely available to help prevent serious illness in persons with mild or moderate COVID-19.
- There is scientific evidence that [antiviral treatment](#) of outpatients at risk for severe COVID-19 may reduce the risk of hospitalization and death.
- COVID-19 therapeutics should be considered for any COVID-19 patient who meets the eligibility criteria.
- This fact sheet summarizes current information about **Lagevrio** eligibility and effectiveness. The FDA's [Fact Sheet for Healthcare Providers](#) is the source of complete information on this COVID-19 therapeutic.

What is Lagevrio?

- Lagevrio (molnupiravir) is an oral antiviral authorized for treatment of mild-moderate COVID-19 illness.
- Patients take 4 capsules twice a day for 5 days. Lagevrio should be administered as early as possible following the diagnosis of COVID-19 and needs to be initiated within 5 days of symptom onset.

Who is eligible for Lagevrio?

- Lagevrio is for adults 18 years and older who are at high risk for developing serious COVID-19 disease including hospitalization and/or death. Lagevrio should be considered for non-hospitalized patients who meet all of the following criteria:
 - Test positive for SARS-CoV-2 (with PCR or antigen test, including at-home tests)
 - Have symptoms consistent with mild-to-moderate COVID-19
 - Have one or more [risk factors](#) for severe COVID
 - Alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.
- Please see the [FDA Fact Sheet for Healthcare Providers](#) for additional information on Lagevrio eligibility criteria and risks associated with use.

Who is considered to have a risk factor for severe COVID-19?

- Per the current [CDC's Interim Clinical Considerations for COVID-19 Treatment in Outpatient guidelines](#), risk factors include:
 - [Age over 50 years](#), with risk increasing substantially at age ≥ 65 years
 - [Being unvaccinated](#) or not being up to date on [COVID-19 vaccinations](#)
 - [Specific medical conditions and behaviors](#)

Does Lagevrio work? Why prescribe a medication for mild-moderate COVID-19?

- Antiviral treatment of outpatients at risk for severe COVID-19 may reduce the risk of hospitalization and death.
- In [clinical trials done prior to authorization](#), Lagevrio was associated with an adjusted relative risk reduction of 30% in all-cause hospitalization or death through Day 29¹.
- Observational data, including from Israel² and Hong Kong³, is consistent with benefit in high-risk patients:
 - 46% risk reduction in hospitalizations and death compared to the untreated for patients 75 and older²
 - 49% risk reduction in death compared to non-users³

References

¹[Molnupiravir for Oral Treatment of Covid-19 in Nonhospitalized Patients](https://www.nejm.org/doi/full/10.1056/NEJMoa2116044), <https://www.nejm.org/doi/full/10.1056/NEJMoa2116044>

²Ronza Najjar-Debbiny et al. *Clinical Infectious Diseases*, 2022;, ciac781, [Effectiveness of Molnupiravir in High-Risk Patients](https://doi.org/10.1093/cid/ciac781), <https://doi.org/10.1093/cid/ciac781>

³Carlos K.H. et al. [Lancet Infectious Disease 2022](https://doi.org/10.1016/S1473-3099(22)00507-2); doi: [https://doi.org/10.1016/S1473-3099\(22\)00507-2](https://doi.org/10.1016/S1473-3099(22)00507-2)

What is the current supply of Lagevrio? Do I need to prioritize prescribing based on supply?

- There is currently ample supply of Lagevrio.
- Lagevrio should be considered as a therapeutic alternative for any COVID-19 positive patient who meets the eligibility criteria and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

How does a patient obtain Lagevrio if they need it?

- An individual's healthcare provider is the best first option for assessment and prescribing for patients who test positive for SARS-CoV-2.
- Oral antivirals, including Lagevrio, are now available at more than 40,000 locations nationwide.
- For individuals who do not have timely access to their own healthcare provider, there are more than 2,700 "[Test-to-treat](#)" sites where patients can get tested, assessed for COVID-19 therapeutic eligibility, and have their prescription filled. Telehealth options are also widely available.

Are there any warnings or precautions that should be taken when prescribing Lagevrio?

- Yes, health care providers and patients must be aware of the following warnings and precautions:
 - Lagevrio is not recommended for use during pregnancy because of risk it may cause fetal harm. Prior to initiating treatment with Lagevrio, health care providers should assess whether an individual of childbearing potential is pregnant or not, if clinically indicated.
 - Individuals of reproductive potential are advised to use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for appropriate time after the last dose per section 8.3 in the [Fact Sheet for Healthcare Providers](#).
 - Breastfeeding is not recommended during treatment with Lagevrio and for 4 days after final dose.
 - Hypersensitivity reactions, including anaphylaxis, have been reported with Lagevrio. Please refer to the Lagevrio fact sheet for health care providers for additional information on warnings and precautions

Are lab results required before a patient can be prescribed Lagevrio?

- Patients must test positive for SARS-CoV-2 to be eligible; PCR or antigen tests, including at-home tests, are acceptable.
- Licensed physicians and advanced practice providers are not required to perform additional laboratory testing when prescribing Lagevrio. Providers should use clinical judgement to determine if labs are necessary.

Can patients take Lagevrio if they are taking other medications? Are there situations where dosing adjustments are necessary?

- No drug interactions have been identified based on the limited available data.
- No dosage adjustment is recommended based on renal or hepatic impairment or in geriatric patients.

Where can I get more information?

- Visit us online at [ASPR](https://aspr.hhs.gov/COVID-19) (<https://aspr.hhs.gov/COVID-19>); email any questions to COVID19therapeutics@hhs.gov.
 - [NIH Therapeutic Management of Non-hospitalized Adults With COVID-19](#)
 - FDA [fact sheet for health care providers](#) on Lagevrio
 - [COVID-19 therapeutics locator](#)
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- LAGEVRIO has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate; and
 - The emergency use of LAGEVRIO is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.