ASPR Administration for Strategic Preparedness & Response

Information Sheet - Lagevrio Eligibility and Effectiveness

- 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.
- **Lagevrio (molnupiravir)** is an antiviral option for the treatment of mild to moderate COVID-19 in eligible adult patients with a current diagnosis of mild to moderate COVID-19 who are at high risk for progression to severe COVID-19, and for whom alternative COVID-19 treatment options approved or authorized by the U.S. Food and Drug Administration (FDA) are not accessible or clinically appropriate.
- COVID-19 treatments 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 to 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:
  - Have a current diagnosis of mild to moderate COVID-19 and are within 5 days of symptom onset,
  - Have one or more risk factors for severe COVID-19, **AND**
  - Alternative COVID-19 treatment options approved or authorized by 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 Centers for Disease Control and Prevention's Interim Clinical Considerations for COVID-19 Treatment in Outpatient guidelines, risk factors include:
  - **Age 50 years or older, 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 to 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 29.[1]
- Observational data, including from Israel[2] and Hong Kong,[3] is consistent with benefit in high-risk patients:
  - 46% risk reduction in hospitalizations and death compared to the untreated for patients 75 and older[2]
  - 49% risk reduction in death compared to non-users[3]

References

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

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

[3]Carlos K.H. et al. *Lancet Infectious Disease* 2022; doi: 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 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 health care provider is the best first option for assessment and prescribing for patients who have symptoms consistent with COVID-19.
- 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 health care 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, if clinically indicated.
  - Individuals with 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.

How is Lagevrio administered?

- The dosage in adult patients is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food, starting within 5 days of symptom onset. For administration via certain feeding tubes, refer to the FDA Fact Sheet on Lagevrio.

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

- 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 https://aspr.hhs.gov/lagevrio
- Email any questions to COVID19therapeutics@hhs.gov.
- NIH Therapeutic Management of Non-hospitalized Adults With COVID-19
- FDA Fact Sheet for Healthcare Providers on Lagevrio
- COVID-19 therapeutics locator

LAGEVRIO has not been approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization, 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.