# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Coronavirus – Oral Medications for Treatment of Coronavirus Disease 2019 (COVID-19) Drug Quantity Management Policy – Per Days
- Lagevrio™ (molnupiravir capsules – Merck)
- Paxlovid™ (nirmatrelvir tablets; ritonavir tablets [co-packaged] – Pfizer)

**REVIEW DATE:** 09/07/2022

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## OVERVIEW

Paxlovid contains nirmatrelvir tablets (a SARS-CoV-2 [severe acute respiratory syndrome coronavirus 2] main protease inhibitor) co-packaged with ritonavir tablets (a cytochrome P450 [CYP]3A inhibitor).[2] Paxlovid was issued Emergency Use Authorization for the treatment of **mild to moderate coronavirus disease 2019 (COVID-19) in patients ≥ 12 years of age** weighing ≥ 40 kg with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Lagevrio is a nucleoside analogue that inhibits SARS-CoV replication by viral mutatgenesis.[1] It was issued Emergency Use Authorization for the treatment of **mild to moderate COVID-19 in adults** with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19, including hospitalization and death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. Lagevrio is not for use in patients < 18 years of age.

For both drugs, limitations of authorized use include the following:[1,2]
- Paxlovid and Lagevrio are not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19. For Lagevrio, benefit of treatment has not been observed when treatment was initiated after hospitalization due to COVID-19.
- Paxlovid and Lagevrio are not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- Paxlovid and Lagevrio are not authorized for use longer than 5 consecutive days.

Of note, the Centers for Disease Control and Prevention states that available evidence suggests that reinfection with SARS-CoV-2 with the same virus variant as the initial infection or reinfection with a different variant are both possible; early reinfection within 90 days of the initial infection can occur.[3]

## Dosing

The recommended dose is as follows:[1,2]
- Paxlovid: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily (BID) for 5 days. Nirmatrelvir must be co-administered with ritonavir. Failure to correctly co-administer nirmatrelvir with ritonavir may result in plasma levels of nirmatrelvir that are insufficient to achieve the desired therapeutic effect.
  - Renal impairment: No dose adjustment is required for patients with mild renal impairment. In patients with moderate renal impairment, the recommended dose of Paxlovid is 150 mg nirmatrelvir (one 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) BID for 5 days. Use of Paxlovid is not recommended in patients with severe renal impairment.
- Lagevrio: 800 mg (four 200-mg capsules) taken orally every 12 hours for 5 days.

Treatment with Paxlovid or Lagevrio should be initiated as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. Completion of the full 5-day treatment course and continued isolation

in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2. Should a patient require hospitalization after starting treatment, the patient may complete the full 5-day treatment course per the healthcare provider's discretion.

## Availability

Paxlovid is supplied in two different dose-packs (cartons)[2]:

- Carton containing 30 tablets divided in five daily-dose blister cards. Each daily blister card contains four nirmatrelvir 150 mg tablets and two ritonavir 100 mg tablets.
- Carton containing 20 tablets divided in five daily-dose blister cards. Each daily blister card contains two nirmatrelvir 150 mg tablets and two ritonavir 100 mg tablets.

Lagevrio is supplied as 200-mg capsules packaged in a bottle of 40 capsules.[1]

## POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of oral medications for the treatment of COVID-19. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below. All approvals will be reviewed by a clinician (nurse or pharmacist).

**Automation:** None.

**Drug Quantity Limits**

| Product | Strength/Dosage Form/Carton Size | Maximum Quantity per 180 Days |
|---|---|---|
| Paxlovid™ (nirmatrelvir tablets; ritonavir tablets [co-packaged]) | 30 tablet carton (contains five daily-dose blister cards containing four nirmatrelvir 150 mg tablets and two ritonavir 100 mg tablets each) | 30 tablets (1 carton of 5 blister cards) |
| | 20 tablet carton (contains five daily-dose blister cards containing two nirmatrelvir 150 mg tablets and two 100 mg tablets each) | 20 tablets (1 carton of 5 blister cards) |
| Lagevrio™ (molnupiravir capsules) | 200 mg capsules (bottles of 40 capsules each) | 40 capsules |

## CRITERIA

Paxlovid tablets

**1.** Approve a one-time override for a second course of treatment (either one 30 tablet carton or one 20 tablet carton) if the patient meets BOTH of the following (A and B):
   **A)** Patient has a repeat diagnosis of COVID-19; AND
   Note: This is a second diagnosis unrelated to the initial diagnosis of COVID-19 which was treated with Paxlovid.
   **B)** At least 90 days have elapsed since completion of the initial course of Paxlovid for treatment of COVID-19.

Lagevrio capsules

**1.** Approve a one-time override for a second course of treatment (40 capsules) if the patient meets BOTH of the following (A and B):

**A)** Patient is has a repeat diagnosis of COVID-19; AND
Note: This is a second diagnosis unrelated to the initial diagnosis of COVID-19 which was treated with Lagevrio.

**B)** At least 90 days have elapsed since completion of the initial course of Lagevrio for treatment of COVID-19.

## REFERENCES

1. Lagrevrio™ capsules [Fact Sheet, Emergency Use Authorization]. Whitehouse Station, NJ: Merck; August 2022. Available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs. Accessed on September 6, 2022.
2. Paxlovid™ tablets [Fact Sheet, Emergency Use Authorization]. New York, NY: Pfizer; August 2022. Available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs. Accessed on September 6, 2022.
3. Clinical considerations for care of children and adults with confirmed COVID-19: reinfection. Centers for Disease Control and Prevention Web site. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/clinical-considerations-reinfection.html. Updated May 27, 2022. Accessed on September 2, 2022.