Anti-COVID 19 Agents Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

FDA APPROVED INDICATIONS[1,2]

Agent(s)	Indication(s)
Lagevrio™ (molnupiravir) Capsule	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 authorized by FDA are not accessible or clinically appropriate Limitations of Authorized Use: Molnupiravir is not authorized - For use in patients less than 18 years of age - For initiation of treatment in patients requiring hospitalization due to COVID-19. Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19 - For use longer than 5 consecutive daysFor pre-exposure or post-exposure prophylaxis for prevention of COVID-19
Paxlovid™ (nirmatreivir/ ritonavir) Tablet	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death Limitations of Authorized Use: - Paxlovid is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19 - Paxlovid is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 - Paxlovid is not authorized for use longer than 5 consecutive days

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Data currently indicates that prior infection with COVID-19 does provide some protection from reinfection. Some studies find that prior infection reduces the risk of infection by 80-85% for 6-7 months.[3,4] Others find that reinfections are rare events and that persons there is minimal risk of reinfection for at least 8 months after the primary infection.[5]

Safety

Molnupiravir has no FDA labeled contraindications based on the limited available data on the emergency use molnupiravir authorized under the EUA.[1]

Paxlovid has the following contraindications:[2]

- History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components.
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions.
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.

References

1. Molnupiravir Fact Sheet for Healthcare Providers: Emergency Use Authorization for Molnupiravir. Merck & Co., Inc. February 2023.
2. Paxlovid Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid. Pfizer Labs. February 2023.
3. Hall VJ, Foulkes S, Charlett A, et al. SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN). Lancet. 2021;397(10283):1459. Epub 2021 Apr 9.
4. Hansen CH, Michlmayr D, Gubbels SM, et al. Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study. Lancet. 2021;397(10280):1204. Epub 2021 Mar 17.
5. Leidi A, Koegler F, Dumont R, et al. SEROCoV-POP study group, Risk of Reinfection After Seroconversion to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2): A Population-based Propensity-score Matched Cohort Study. Clinical Infectious Diseases, February 2022, Pages 622-629, https://doi.org/10.1093/cid/ciab495.\\

Anti-COVID19 Agents Quantity Limit

OBJECTIVE
The Anti-COVID 19 Agents Quantity Limit program is to help prevents overuse of these agents.

TARGET AGENT(S)
Molnupiravir
Paxlovid

PROGRAM QUANTITY LIMIT TARGET AGENTS – RECOMMENDED LIMITS

Brand (generic)	GPI	Quantity Limit
Lagevrio (molnupiravir)		
200 mg capsules	12700046000120	40 capsules/30 days (1 course of therapy per month)
Paxlovid (nirmatrelvir/ritonavir)		
150 mg/100 mg tablet	1299000255B710	20 tablets/30 days (1 course of therapy per month)
150 mg/100 mg tablet	1299000255B720	30 tablets/30 days (1 course of therapy per month)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Quantities above the program quantity limit for the
Target Agent(s) will be approved when ALL of the following are met:

1. The patient is using the requested agent for a COVID-19 reinfection
   AND
2. The patient's age is within FDA Emergency Use Authorization (EUA) for the requested indication for the requested agent
   AND
3. The requested agent is NOT being used to extend treatment beyond the maximum FDA EUA treatment regimen for the requested indication
   AND
4. The patient will NOT be using the requested agent in combination with another agent in this program for the requested indication
   AND
5. The requested quantity (dose) does NOT exceed the maximum FDA EUA dosing for the requested indication

Length of Approval: 1 additional course of therapy for 1 month