

CMS Issues Guidance on Prescription Oral Antivirals for COVID-19

- On January 4, 2024, the Centers for Medicare & Medicaid Services (CMS) issued updated guidance titled “Introduction of Prescription Oral Antivirals for COVID-19 to the Commercial Market” to amplify the guidance title, “Part D Coverage of Oral Antivirals for COVID-19,” issued on November 4, 2022.
- CMS is providing guidance for Part D sponsors to ensure claims for oral antivirals are processed appropriately to ensure beneficiary access at no cost sharing for as long as possible and to utilize supply that has already been procured by the U.S. Government (USG).
- Oral antivirals for COVID-19 that meet the statutory requirements of the Social Security Act must be covered by Part D plans, either as a formulary product or through the formulary exception process. CMS encourages Part D sponsors to add at least one oral antiviral for COVID-19 that meets the definition of a Part D drug to their 2024 formulary on a preferred or \$0 cost-sharing tier. As of November 1, 2023, Paxlovid (nirmatrelvir and ritonavir) and Lagevrio (molnupiravir) were officially added to the commercial market and there are now two distinct supplies of each medication in circulation—the USG-distributed supply and the commercial supply. Beginning in Contract Year 2025, CMS will look for inclusion of oral antivirals for COVID-19 that meet the definition of a Part D drug as part of the annual formulary and bid review process.
- Commercial Paxlovid is the FDA-approved, New Drug Application (NDA)-labeled product. Commercial Lagevrio is EUA-labeled with a distinct NDC from the USG-distributed, EUA-labeled product. This distinction will allow plans and processors to identify which product is being dispensed by the pharmacy when claims are submitted.
- Part D sponsors should continue processing claims submitted for USG-distributed, EUA-labeled Paxlovid and Lagevrio as long as USG-distributed, EUA-labeled supply is available.
- Through December 31, 2024, Medicare beneficiaries can access commercial, NDA-labeled Paxlovid at \$0 cost sharing through the patient assistance program operated by Pfizer as part of an agreement with HHS for USG-procured Paxlovid. See the Guidance for additional details about processing claims for commercial

Paxlovid.

- Part D coverage rules continue to apply to oral antiviral drugs for COVID-19 available under an emergency use authorization (EUA) until December 31, 2024. Part D enrollees will be able to obtain commercial Lagevrio through their Part D benefit, subject to Part D coverage rules, formulary status, and applicable Part D cost sharing.



More on This Topic:

- [Guidance](#)

For questions, please reach out to [Vicky Jucelin](#).

AMCP | 675 North Washington Street, Suite 220 | Alexandria, VA, 22314

[Manage Preferences](#)

