



CENTERS FOR MEDICARE & MEDICAID SERVICES

DATE: November 23, 2021

TO: All Part D Sponsors

FROM: Chiquita Brooks-LaSure, Administrator

SUBJECT: Permissible Flexibilities Related to Oral Antiviral Drugs for Treatment of COVID-19 that May Receive U.S. Food and Drug Administration Emergency Use Authorization *and* are Procured by the U.S. Government

The Centers for Medicare & Medicaid Services (CMS) is issuing this guidance to inform Part D sponsors of permissible flexibilities during the COVID-19 public health emergency (PHE) related to oral antiviral drug(s) for COVID-19 if such drug(s) become available under a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) (referred to in this memorandum as EUA oral antiviral drugs) *and* are procured by the U.S. Government (USG).

If the FDA authorizes oral antiviral drug(s) for emergency use for COVID-19, we anticipate those EUA oral antiviral drug(s) will initially be made available for dispensing at sites that will include pharmacies that have provider agreements with the USG to dispense the drug in compliance with the terms and conditions of the authorization. CMS will provide a list of these pharmacies, including National Provider Identifier (NPI), on the Health Plan Management System as soon as it is available. CMS does not expect that all pharmacies participating in Part D networks will be included in these contractual arrangements to dispense the USG-procured EUA oral antiviral drugs.

CMS strongly encourages Part D sponsors to take advantage of these flexibilities to help provide their enrollees with timely access to these life-saving drugs. Use of these flexibilities will also allow Part D sponsors to keep informed of any enrollee utilization to better manage patient care.

Specifically, CMS will exercise enforcement discretion with respect to USG-procured EUA oral antiviral drugs to permit Part D sponsors to: 1) pay pharmacy claims for dispensing fees without enrollee cost sharing; and 2) report prescription drug events (PDEs) for the dispensing fee claims.

- **Paying Dispensing Fees:** While certain USG-procured oral antiviral drug(s) will be made available at no cost to pharmacies, the procurement does not include payment of a dispensing fee to pharmacies. Part D sponsors may pay a dispensing fee to pharmacies that submit claims for these drugs. No ingredient cost can be paid on such claims. The USG has procured doses of certain oral antiviral drugs so that they can be available to the applicable patient population free of charge during the COVID-19 PHE. Accordingly, Part D sponsors should not charge enrollee

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cost sharing on dispensing fees paid to the pharmacies.

CMS urges Part D sponsors to pay dispensing fees for USG-procured EUA oral antiviral drugs during the COVID-19 PHE sufficient to ensure eligible patients can readily access these drugs at available pharmacies. CMS encourages sponsors to consider paying a dispensing fee for these drugs that may be higher than a sponsor's usual negotiated dispensing fees given the unique circumstances during the PHE. Should a sponsor choose to pay a higher dispensing fee, we expect this fee to be paid in a uniform manner.

We encourage plans to consider allowing out-of-network pharmacies to bill for dispensing fees for USG-procured EUA oral antiviral drugs if it will help improve access in certain areas.

- **Reporting PDEs:** Part D sponsors will report these dispensing fees as a Covered D Plan Paid Amount (CPP) for all plan types and regardless of beneficiary low-income subsidy status. Sponsors will populate the DRUG COVERAGE STATUS CODE with 'C'.

Sponsors should consult the NCPDP Emergency Preparedness Guidance for "Billing for Reimbursement of a Free Product (No Associated Cost) with No Administration Fee" as they prepare to implement these changes.

Please direct any questions regarding this guidance to Part D Policy at PartDPolicy@cms.hhs.gov or to pdejan2011@cms.hhs.gov for PDE questions.

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