DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Center for Medicare

DATE: January 20, 2022

TO: All Part D Sponsors

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

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

On November 23, 2021 the Centers for Medicare & Medicaid Services (CMS) issued 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).[1] This memo provides the following instruction with regard to prescription drug event (PDE) reporting of dispensing fees associated with EUA oral antiviral drugs as well as other information related to PDE reporting.

Reporting Dispensing Fees. As mentioned in the November 2021 guidance, Part D sponsors will report the entire dispensing fee associated with a USG-procured EUA oral antiviral drug as a Covered D Plan Paid Amount (CPP) for all plan types, including Employer Group Waiver Plans (EGWPs), and regardless of beneficiary low-income subsidy status. CMS continues to encourage 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. We have become aware plans may process increased dispensing fees through the use of two fields: (1) the dispensing fee field for the standard dispensing fee; AND (2) by adding the additional amount into a separate field (Incentive Fee) within the National Council for Prescription Drug Programs, (NCPDP) Telecommunication standard. To support the processing of increased dispensing fees, Part D sponsors may use field 41, Vaccine Administration Fee, to report the dispensing amount over and above what will be reported in field 30, Dispensing Fee Paid, on the PDE for EUA oral antiviral drugs procured by the USG.

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[1] See Renewal of Determination That A Public Health Emergency Exists.

CMS will update the Drug Data Processing System (DDPS) to ensure its PDE editing logic will allow the reporting of these additional dispensing fee amounts for USG-procured EUA oral antiviral medications in field 41. In addition, CMS will change the name of field 41 to Vaccine Administration Fee or Additional Dispensing Fee. CMS will notify the industry once these updates have been completed.

Other PDE Related Information. Part D sponsors will update the Total Gross Covered Drug Cost (TGCDC) Accumulator after processing a claim for a USG-procured EUA oral antiviral drug. As there are no beneficiary incurred costs on the claim for a USG-procured EUA oral antiviral drug, the True Out-Of-Pocket (TrOOP) Accumulator will not be increased after processing a claim for a USG-procured EUA oral antiviral drug.

Part D sponsors will populate the Brand/Generic Code on the PDE with 'B' for a USG-procured EUA oral antiviral drug. The Tier on the PDE will be blank, and the Formulary Code on the PDE will be populated with 'N'.

As noted above, the cost of the drug (dispensing fee and any additional dispensing fee amount reported in field 41) is included in Total Gross Covered Drug Costs and, therefore, is counted toward satisfying the deductible under the defined standard benefit or the plan defined deductible. Plan sponsors will report these PDEs with deductible phase benefit indicators ('D') on the PDE.

Please direct any questions regarding this guidance to pdejan2011@cms.hhs.gov.