DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: November 4, 2022

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

FROM: Amy Larrick Chavez-Valdez
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SUBJECT: Part D Coverage of Oral Antivirals for COVID-19

The Centers for Medicare & Medicaid Services (CMS) is issuing this guidance to inform Part D sponsors of expectations related to oral antiviral drugs for COVID-19 in the event that such drug(s) receive U.S. Food and Drug Administration (FDA) approval. This memo also includes guidance on potential scenarios addressing oral antiviral drugs for COVID-19 that are available only under an Emergency Use Authorization (EUA) and are still in circulation, the U.S. Government (USG) procurement status of available EUA or FDA-approved oral antivirals, and continued flexibilities related to USG-procured products once the COVID-19 public health emergency (PHE) declared under section 319 of the Public Health Service Act (PHSA) ends. COVID-19 treatments are widely available and critical for preventing severe illness from the virus. Where possible, Part D sponsors should ensure their enrollees are aware of the availability of treatments and seek to eliminate hurdles to access. Part D sponsors may also find the recent Issue Brief by the Office of the Assistant Secretary for Planning and Evaluation, "Understanding Coverage Considerations for COVID-19 Vaccines and Treatments," instructive.[1]

Part D Formulary Inclusion and Tier Placement

Products available only under an EUA do not meet the definition of a Part D drug and cannot be covered by Part D plans. However, oral antivirals for COVID-19 that meet the statutory requirements at section 1860D-2(e) of the Social Security Act and are not otherwise excluded from coverage must be covered by Part D plans upon FDA approval, either as a formulary product or through the formulary exception process consistent with 42 CFR 423.578(b).

As stated in chapter 6 of the Prescription Drug Benefit Manual, § 30.1.5 "Formulary Management," a Part D sponsor's Pharmacy and Therapeutics (P&T) committee is expected to make a reasonable effort to review new FDA-approved drugs within 90 days and decide on

[1] Trinidad Beleche, Laina Bush, Kenneth Finegold, Teresa Manocchio, Sarada Pyda, Lok Wong Samson, Benjamin D. Sommers, "Understanding Coverage Considerations for COVID-19 Vaccines and Treatments," August 31, 2022. Available at https://aspe.hhs.gov/reports/covid-19-vaccines-treatments.

formulary placement within 180 days of the drug's release on the market. Drugs within the six protected classes are subject to an expedited review process and a decision within 90 days of release on the market. Although oral antivirals for COVID-19 are not protected class drugs, CMS encourages Part D sponsors to have their P&T committees review any new FDA-approved oral antivirals for COVID-19 within this expedited timeframe given the unique circumstances of the COVID-19 pandemic. Although oral antivirals have been available and distributed under an EUA, CMS considers the review timeframe to begin based on the market release of an FDA-approved product since Part D sponsors' P&T committees should have access to a product's FDA-approved label to inform formulary decisions. This does not preclude Part D sponsors' P&T committees from beginning their review ahead of any FDA approval based on available scientific evidence.

CMS expects Part D sponsors will add at least one oral antiviral for COVID-19 to their Part D formularies in the event such drug(s) receive FDA approval because there currently are no formulary alternatives. We encourage sponsors to place at least one of these products on a preferred or $0 cost-sharing tier, if available in the plan benefit structure, in order to maximize access to these life-saving drugs in the ongoing fight against COVID-19. Part D sponsors may wish to consider adding all such products, as they become available, to their formularies and placing them on a preferred or $0 cost-sharing tier since there could be supply disruptions as distribution moves from a USG allotment system to commercial markets.

Utilization Management (UM) Edits

CMS will permit Part D sponsors to apply utilization management (UM) edits to oral antivirals for COVID-19 that are added to their formularies because such edits may be warranted (e.g., quantity limits [QLs] to prevent stockpiling). However, CMS believes that the risk of delaying therapy, potentially to the point that the therapy is no longer indicated, due to UM requirements that cannot be resolved at point-of-sale (POS) needs to be weighed against the benefit of UM edits intended to determine medical necessity or confirm use for a medically accepted indication. CMS prefers that Part D sponsors leverage available technology to implement "soft edits" to guide appropriate use but that are resolvable at POS. If a sponsor identifies any suspicious claims activity suggesting fraud, waste, or abuse, addition of UM edits may be warranted. QLs and prior authorization (PA) criteria will be reviewed by CMS consistent with chapter 6 § 30.2.2.1 "Utilization Management Edits Requiring CMS Submission and Approval" and will not be approved if deemed to be overly restrictive or inconsistent with the FDA-approved label.

Coverage Determination Timeframe

The oral antivirals for COVID-19 currently available under an EUA require initiation of treatment within 5 days of symptom onset. If a COVID-19 oral antiviral is approved by the FDA, it is possible that the label for such product may similarly indicate a need to initiate treatment within a specified number of days from symptom onset.

Part D plans are required to establish and maintain procedures for processing coverage determinations as expeditiously as the enrollee's health condition requires consistent with 42 CFR § 423.566. Standard coverage determinations (42 CFR § 423.568) require plan decisions

within 72 hours and expedited initial coverage determinations (42 CFR § 423.570) require plan decisions within 24 hours. Part D plan sponsors are required to process a coverage determination request under the expedited timeframe when the prescriber indicates, or the plan decides, that applying the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. Therefore, Part D sponsors must expedite coverage determination requests for oral antivirals for COVID-19 if the standard decision timeframe risks delaying therapy to the point the drugs are no longer indicated, which would be the case for the oral antivirals for COVID-19 currently available under an EUA. Note that the expedited timeframes apply to formulary exceptions, PA exceptions, and whether or not an enrollee has satisfied PA or other UM requirements.

Managing USG-Procured and Commercially Available Product Supply

It is possible that USG-procured EUA oral antivirals for COVID-19 will be in circulation at the same time pharmacies are able to procure FDA-approved version(s) of the same drug product(s). Part D sponsors will need to consider the information available at that time to distinguish products and work with their network pharmacies to assure that claims adjudicate appropriately.

USG-procured EUA oral antivirals for COVID-19 that remain in circulation must be dispensed consistent with terms of agreement with the USG, and the Ingredient Cost Submitted for the free product should be submitted as $0.00.[2] Dispensing fees may be billed to Part D plans consistent with guidance issued in the November 23, 2021 memorandum "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."[3] If the USG continues to procure FDA-approved products, Part D sponsors will continue to pay only for associated dispensing fees consistent with Part D sponsors' and pharmacies' contractual agreements.

For an FDA-approved product that is not USG-procured, Part D sponsors will be responsible for covering both the drug cost and dispensing fee like any other Part D drug.

Continued Flexibilities for USG-Procured EUA Oral Antivirals for COVID-19 Following the End of the COVID-19 PHE

Should the COVID-19 PHE declared under section 319 of the PHSA end while USG-procured oral antivirals for treatment of COVID-19 remain available under an EUA, Part D sponsors maintain the previously stated flexibilities to 1) pay pharmacy claims for dispensing fees without enrollee cost sharing; and 2) report prescription drug events (PDEs) for the dispensing fee claims.[2]

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[2] Refer to the current version of the National Council for Prescription Drug Programs (NCPDP) Emergency Preparedness Guidance. Available at https://www.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessGuidance.pdf.

[3] Available at https://www.cms.gov/files/document/hpms-memo-oral-antiviral-guidance.pdf. See also, January 20, 2022 memorandum "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," available at https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-wk-3-january-17-21.

Questions

Please direct any questions regarding this guidance to Part D Policy at PartDPolicy@cms.hhs.gov. Questions on coverage determination processes should be submitted to https://appeals.lmi.org/dapmailbox.