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**DATE:** January 4, 2024

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

**FROM:** Vanessa S. Duran, Acting Director  
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**SUBJECT:** Introduction of Prescription Oral Antivirals for COVID-19 to the Commercial Market

The Centers for Medicare & Medicaid Services (CMS) is issuing this guidance to expand upon the guidance provided in the November 4, 2022 memorandum,<sup>1</sup> “Part D Coverage of Oral Antivirals for COVID-19,” in the context of the transition of oral antivirals for COVID-19 to the commercial market.

On October 20, 2023, the Administration for Strategic Preparedness & Response (ASPR) released new guidance,<sup>2</sup> “Sunsetting the U.S. Government COVID-19 Therapeutics Distribution Program,” which detailed the process the U.S. Government (USG) will take to wind down distribution of USG-procured oral antivirals through the Federal Retail Pharmacy Therapeutics Program (FRPTP) (also referred to in this memo as “USG-distributed” supply). Paxlovid (nirmatrelvir and ritonavir) and Lagevrio (molnupiravir) officially entered the commercial market on November 1, 2023.

The introduction of Paxlovid and Lagevrio to the commercial market creates two distinct supplies of each medication—the USG-distributed supply and the commercial supply. While ordering for USG-distributed Lagevrio and Paxlovid for most pharmacies ended on November 10, 2023 and December 15, 2023, respectively,<sup>3</sup> a supply of these products remains in circulation. Thus, there will be a period of time during which both USG-distributed and

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<sup>1</sup> Available at <https://www.cms.gov/htpseditcmgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-hpms-memos-archive/hpms-memos-wk-1-november-1-4>

<sup>2</sup> <https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/COVID19-Tx-Transition-Guide.aspx>

<sup>3</sup> After November 10, 2023, USG-distributed Lagevrio may only be ordered by the Health Resources and Services Administration (HRSA), Department of State (DoS), Indian Health Service (IHS), Peace Corps (PC), Bureau of Prisons (BOP), Immigration and Customs Enforcement (ICE), and the National Institutes of Health (NIH). After December 15, 2023, USG-distributed Paxlovid may only be ordered by HRSA, DoS, IHS, PC, BOP, ICE, NIH, Veterans Affairs (VA) and the Department of Defense (DoD).

commercial products are in circulation. CMS is providing guidance and outlining expectations for Part D sponsors to ensure claims for oral antivirals are processed appropriately during, and beyond, this period of time to serve the dual goals of ensuring beneficiary access to these important medications at no cost sharing for as long as possible and utilizing supply that has already been procured by the USG.

Pursuant to section 4131 of the Consolidated Appropriations Act, 2023 (CAA, 2023), prescription oral antivirals for COVID-19 with emergency use authorization (EUA) are included in the definition of a Part D drug until December 31, 2024.<sup>4</sup> Thus, Part D coverage rules apply to oral antiviral drugs for COVID-19 available under an EUA (referred to herein as EUA oral antivirals).

Throughout this memorandum, where reference is made to EUA oral antivirals meeting the definition a Part D drug, we clarify that this definition and the corresponding guidance only apply until December 31, 2024. We also note where previously issued guidance refers to “USG-procured” products, we clarify that “USG-procured” means the same as “USG-distributed” in this memorandum.

#### *Part D Formulary Inclusion and Coverage*

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, either as a formulary product or through the formulary exception process consistent with [42 CFR § 423.578\(b\)](#).

Consistent with the November 4, 2022 memorandum, CMS continues to encourage Part D sponsors to add at least one oral antiviral for COVID-19 that meets the definition of a Part D drug to their Contract Year (CY) 2024 formulary on a preferred or \$0 cost-sharing tier, as available in the plan benefit structure. Part D sponsors may consider the access options described in this memorandum when determining formulary placement and application of utilization management (UM) edits for commercially available oral antivirals for COVID-19. Part D sponsors are permitted to apply UM edits for oral antivirals for COVID-19 that are added to their formulary; however, CMS notes that UM requirements that cannot be resolved at point-of-sale should be weighed against the need to initiate treatment in an expedient manner. CMS prefers that Part D sponsors leverage available technology to implement “soft reject” edits to guide appropriate use but that are resolvable at point-of-sale. UM criteria will be reviewed by CMS consistent with [Chapter 6 § 30.2.2.1](#) “Utilization Management Edits Requiring CMS Submission and Approval” of the Prescription Drug Benefit Manual and will not be approved if deemed to be overly restrictive or inconsistent with the product label.

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<sup>4</sup> Specifically, section 4131 of the CAA, 2023 amended the definition of a covered Part D drug at section 1860D-2(e)(1) of the Social Security Act (42 U.S.C. 1395w-102(e)(1)) to include, until December 31, 2024, oral antiviral drugs that may be dispensed only upon a prescription and are “authorized under section 564 of the Federal Food, Drug, and Cosmetic Act, on the basis of the declaration published in the Federal Register by the Secretary of Health and Human Services on April 1, 2020 (85 Fed. Reg. 18250 et seq.),” which was issued subsequent to the start of the COVID-19 pandemic. <https://www.congress.gov/bill/117th-congress/house-bill/2617/text>

For CY 2025 and beyond, the CMS annual formulary and bid review process will incorporate review of formularies for inclusion of oral antivirals for COVID-19 that meet the definition of a Part D drug.

The commercially available oral antivirals for COVID-19 require initiation of treatment as soon as possible and within 5 days of symptom onset.<sup>5,6</sup> 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 sponsors are required to process a coverage determination request under the expedited timeframe when the prescriber indicates (or when an enrollee requests a coverage determination, 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. Expedited timeframes apply to formulary exceptions (which include requests for non-formulary drugs, as well as requests to have UM requirements waived<sup>7</sup>), and whether or not an enrollee has satisfied prior authorization or other UM requirements.

#### *Identifying USG-Distributed and Commercially Available Product Supply*

Part D sponsors should be aware that the USG-distributed, EUA-labeled Paxlovid and Lagevrio will have distinct National Drug Codes (NDCs) from the commercial products.<sup>2</sup> Commercial Paxlovid will be the FDA-approved, New Drug Application (NDA)-labeled product, whereas commercial Lagevrio will be EUA-labeled with a distinct NDC from the USG-distributed, EUA-labeled product. Therefore, when claims are submitted, plans and processors will be able to identify which product is being dispensed by the pharmacy. These NDCs are listed in Table 1 for reference.

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<sup>5</sup> PAXLOVID Prescribing Information. May 2023. Available from <https://labeling.pfizer.com/ShowLabeling.aspx?id=19599>.

<sup>6</sup> LAGEVRIO Fact Sheet For Health Care Providers. October 2023. Available from <https://www.merck.com/eua/molnupiravir-hcp-fact-sheet.pdf>.

<sup>7</sup> See Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 40.5.2, "Formulary Exceptions," available from <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf>.

*Table 1. Current NDCs for USG-Distributed and Commercially Available Oral Antivirals for COVID-19*

<b>Paxlovid Product</b>	<b>NDCs</b>
USG-distributed Paxlovid (EUA-labeled)	Carton: 0069-0345-30; 0069-1085-30; 0069-1101-20  Blister: 0069-1085-06; 0069-0345-06; 0069-1101-04
Commercial Paxlovid (NDA-labeled) <sup>8</sup>	Carton: 0069-5321-30; 0069-5317-20  Blister: 0069-5321-03; 0069-5317-02
<b>Lagevrio Product</b>	<b>NDCs</b>
USG-distributed Lagevrio (EUA-labeled)	0006-5055-06
Commercial Lagevrio (EUA-labeled)	0006-5055-09

*Processing Claims for USG-Distributed Product*

Part D sponsors are expected to continue processing claims that are submitted for USG-distributed, EUA-labeled Paxlovid and Lagevrio and reporting prescription drug events (PDEs) as described in previous guidance<sup>9,10,11</sup> as long as USG-distributed, EUA-labeled supply is available.

Part D sponsors that process Part D claims from pharmacies that are receiving USG-distributed, NDA-labeled Paxlovid after December 15, 2023,<sup>8</sup> should process claims and report PDE for the USG-distributed, NDA-labeled Paxlovid in the same manner as the USG-distributed, EUA-labeled product. Part D sponsors should work with their network pharmacies that may be receiving USG-distributed, NDA-labeled Paxlovid (e.g., I/T/U pharmacies operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization) to ensure that claims are being submitted correctly since both USG-distributed NDA-labeled and commercial NDA-labeled Paxlovid will have the same NDCs, but claims for the USG-distributed supply will have no ingredient cost<sup>9</sup> and no beneficiary cost sharing.<sup>12</sup>

<sup>8</sup> USG-procured Paxlovid distributed after December 15, 2023, will be the FDA-approved, NDA-labeled product; however, Part D sponsors should note that USG distribution of Paxlovid after December 15, 2023 is limited to HRSA, DoS, IHS, PC, BOP, ICE, NIH, VA, and DoD. See footnote 3.

<sup>9</sup> Refer to the current version of the National Council for Prescription Drug Programs (NCPDP) Emergency Preparedness Guidance, available at <https://www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessGuidance.pdf>.

<sup>10</sup> 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-systemshpms-hpms-memos-archive/hpms-memos-wk-3-january-17-21>.

<sup>11</sup> 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,” available at <https://www.cms.gov/files/document/hpms-memo-oral-antiviral-guidance.pdf>.

<sup>12</sup> <https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/Commercialization-FAQ-Nov2023.aspx>

Since as of December 15, 2023, ordering for USG-distributed oral antivirals for COVID-19 is limited to certain federal entities, CMS will no longer publish the COVID-19 Oral Antiviral Therapeutic Locator List in HPMS.<sup>13</sup>

### *Processing Claims for Commercial Paxlovid*

Through December 31, 2024, Medicare beneficiaries can access commercial, NDA-labeled Paxlovid at \$0 cost sharing through the patient assistance program operated by Pfizer and authorized by the U.S. Department of Health and Human Services (HHS) as part of an agreement between Pfizer and HHS regarding USG-procured Paxlovid (hereafter the USG PAP). The USG PAP is available to Medicare beneficiaries via two pathways, which are discussed in more detail below. The first pathway is available to enrollees of Part D plans that voluntarily choose to facilitate the USG PAP via an agreement with Pfizer. The second pathway is available to all Medicare beneficiaries, regardless of whether they are enrolled in a Part D plan or whether their Part D plan opts to participate in the plan-facilitated pathway.

#### **Part D Plan-Facilitated USG PAP**

- Part D enrollees may obtain commercial, NDA-labeled Paxlovid through their Part D plan at \$0 cost sharing through December 31, 2024, if their Part D sponsor chooses to participate by contracting with Pfizer to provide access through the USG PAP.
- Pfizer has agreed to pay participating Part D sponsors a flat rebate intended to approximate the negotiated price on each claim for commercial Paxlovid that the sponsor pays to pharmacies. Part D sponsors will reconcile the total rebates received to the aggregate negotiated prices paid to pharmacies and report direct and indirect remuneration (DIR) to CMS, consistent with normal reporting and reconciliation rules and processes.
- Under the terms offered by Pfizer, Part D sponsors agreeing to implement the USG PAP must:
  - Add commercial Paxlovid to their formulary without any prior authorization or step therapy requirements. Part D sponsors may implement quantity limits to limit each fill to one full course of therapy. If the Part D plan benefit design does not include a \$0 cost-sharing tier, Part D sponsors can indicate \$0 cost sharing by use of a footnote or other means of communication in their print and online formulary materials required under [42 CFR § 423.2265\(b\)](#) and [\(c\)](#), and [42 CFR § 423.2267\(e\)\(9\)](#).
  - Process in-network claims for commercial Paxlovid at no cost to the enrollee for all dates of service beginning on November 1, 2023, and

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<sup>13</sup> January 7, 2022 HPMS Email, “COVID-19 Oral Antiviral Therapeutic Locator List Posted in HPMS,” available at <https://www.cms.gov/files/document/covid19oralantiviraltherapeuticlocatorlistpostedinhpms.pdf>.

ending on December 31, 2024, and invoice Pfizer for the rebate for all paid claims.

- Process out-of-network claims (i.e., direct member reimbursement requests) for commercial Paxlovid that meet the requirements under [42 CFR § 423.124\(a\)](#) at no cost to the enrollee for all dates of service beginning on November 1, 2023, and ending on December 31, 2024, and invoice Pfizer for the rebate for all paid claims.
- Exclude all amounts paid to pharmacies for commercial Paxlovid from Part D accumulators and Coverage Gap discounts so that enrollees do not progress within or through any phase of the Part D benefit because of these claims.
- Refund enrollees who paid cost sharing for commercial Paxlovid between November 1, 2023 and December 31, 2024 if claims processing systems were not programmed to adjudicate at no beneficiary cost sharing, adjust the reported PDE, Part D accumulators, and Coverage Gap discount payments to reflect the rebate, and invoice Pfizer for the rebate for all paid claims.
- Send an email to [PDE-Operations@cms.hhs.gov](mailto:PDE-Operations@cms.hhs.gov), with “USG PAP” in the subject line, that includes a list of all contracts and plan benefit packages (PBPs) for which the Part D sponsor has reached an agreement with Pfizer to participate in the plan-facilitated USG PAP pathway.
- Ensure that the PDE record reflects all related rebates by reporting them in field 40 on the PDE layout, Estimated Remuneration at Point-of-Sale (POS) Amount (ERPOSA). The dollar value of rebates reported on the PDE must fully offset the PDE-reported negotiated price, meaning that ERPOSA must equal 100 percent of the negotiated price of the drug, and the ingredient cost, dispensing fee, vaccine administration fee, additional dispensing fee reported in the vaccine administration fee field, and sales tax must all be equal to zero. This is to ensure the beneficiary receives Paxlovid with no out-of-pocket cost or progression through the Part D benefit as a result of the claim. Should a Part D sponsor need additional time to make the system changes needed to submit PDE records consistent with this guidance, CMS will exercise enforcement discretion with respect to the 30-day submission timeframe for initial PDE records for Paxlovid with dates of service in 2024. These PDE records must be submitted by the PDE submission deadline for the 2024 Part D payment reconciliation which is currently scheduled for late June 2025.<sup>14</sup>

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<sup>14</sup>[https://www.csscooperations.com/internet/csscw3\\_files.nsf/F2/2024%20Annual%20PDE%20Data%20Submission%20Timeline%20Final%2009.28.2023.pdf/\\$FILE/2024%20Annual%20PDE%20Data%20Submission%20Timeline%20Final%2009.28.2023.pdf](https://www.csscooperations.com/internet/csscw3_files.nsf/F2/2024%20Annual%20PDE%20Data%20Submission%20Timeline%20Final%2009.28.2023.pdf/$FILE/2024%20Annual%20PDE%20Data%20Submission%20Timeline%20Final%2009.28.2023.pdf)

- Include the USG PAP related rebates in the DIR Report for Payment Reconciliation, consistent with current CMS guidance.<sup>15</sup>
- This pathway ensures that Part D enrollees do not inadvertently pay their Part D plan cost sharing that otherwise would apply because they did not enroll in the standalone USG PAP (the other pathway for Medicare beneficiaries to access commercial, NDA-labeled Paxlovid at \$0 cost sharing, discussed in more detail below) or because the Part D enrollee’s preferred pharmacy is not participating in the standalone USG PAP.
- If a Part D sponsor chooses to contract with Pfizer to offer this pathway, the plan enrollee still can enroll in the standalone USG PAP discussed below and obtain commercial Paxlovid for free without involving their Part D plan in the claim.
- Pfizer is contacting its existing Medicare customers to discuss the process of contracting with Pfizer to facilitate the USG PAP. Part D sponsors that have not already been contacted by Pfizer may email [Craig.M.Masker@pfizer.com](mailto:Craig.M.Masker@pfizer.com).

### **Standalone USG PAP Operated By Pfizer**

- The standalone USG PAP pathway for commercial Paxlovid launched December 1, 2023, and will be available for Medicare beneficiaries through December 31, 2024.<sup>16</sup> Medicare beneficiaries can access commercial Paxlovid through the standalone USG PAP operated by Pfizer regardless of whether their Part D plan is participating in the Part D Plan-facilitated USG PAP pathway previously described.
- Pharmacies contracted to participate in the standalone USG PAP will submit claims directly to the USG PAP operated by Pfizer for Medicare beneficiaries who have enrolled in the standalone USG PAP.<sup>17</sup> Claims submitted to the standalone USG PAP may not be submitted to a Part D plan.
- Part D plans will not coordinate with or submit PDE for claims billed to the standalone USG PAP, as the standalone USG PAP will operate outside the Part D benefit.

Part D sponsors that have not contracted to facilitate the USG PAP under the first pathway should note that since Paxlovid meets the definition of a Part D drug under section 1860D-2(e) of the Social Security Act, it is not permissible to deny claims for Paxlovid simply because an alternative pathway for coverage exists via the standalone USG PAP operated by Pfizer. These

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<sup>15</sup> October 14, 2022 memorandum, “Reporting Estimated Remuneration Applied to the Point-of-Sale Price,” available at <https://www.cms.gov/files/document/erposamemo508g.pdf>.

<sup>16</sup> For information about the PAXCESS™ patient support program operated by Pfizer, visit <https://www.paxlovid.com/paccess>.

<sup>17</sup> Part D sponsors should note that Pfizer is also offering a Paxlovid copay assistance program for individuals with commercial insurance. Consistent with the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)), Part D enrollees are not eligible for such a copay assistance program that would subsidize beneficiary cost-sharing amounts under the Part D benefit.

sponsors may implement message-only alerts or soft reject edits to alert pharmacists to availability of the standalone USG PAP operated by Pfizer as long as the pharmacist can override the edit.

- **Part D plans that have not contracted to facilitate the USG PAP and choose to exclude commercial Paxlovid from the formulary** can direct their enrollees to the standalone USG PAP; however, the Part D plan must still process formulary exceptions in accordance with the timeframes and procedures at [42 CFR § 423.566](#), [42 CFR § 423.568](#), and [42 CFR § 423.570](#), as discussed earlier in this memorandum. Enrollees will be responsible for the applicable cost sharing associated with their plan benefit as a result of a favorable coverage determination.
- **Part D plans that have not contracted to facilitate the USG PAP and choose to include commercial Paxlovid on the formulary** may not impose prior authorization requirements for the sole purpose of directing enrollees to the standalone USG PAP operated by Pfizer. Enrollees will be responsible for the applicable cost sharing associated with their plan benefit.

CMS encourages Part D sponsors to provide education and outreach to their enrollees and network pharmacies regarding whether the Part D sponsor will contract with Pfizer to offer Paxlovid at \$0 cost sharing through the Part D plan, or instead, encouraging enrollees and network pharmacies to utilize the standalone USG PAP operated by Pfizer. CMS is reviewing options for communicating this information on Medicare Plan Finder. Pharmacies will not be able to retroactively bill the standalone USG PAP if a Part D enrollee obtains Paxlovid through their Part D benefit and later learns that their Part D plan was not contracted with Pfizer to provide Paxlovid at \$0 cost sharing and that they could have obtained the drug for free. Moreover, Part D sponsors cannot coordinate with, or seek recoveries from, the standalone USG PAP operated by Pfizer.

#### *Processing Claims for Commercial Lagevrio*

Consistent with section 4131 of the CAA, 2023, EUA oral antivirals for COVID-19 meet the definition of a Part D drug until December 31, 2024 and must be covered by Part D plans, either as a formulary product or through the formulary exception process consistent with [42 CFR § 423.578\(b\)](#). Therefore, 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.

While Merck offers a patient assistance program that provides Lagevrio free of charge to eligible patients who, without assistance, could not otherwise afford the product,<sup>18</sup> there is no unique arrangement with the USG for Medicare beneficiaries. See [Chapter 14](#), Appendix E, of the Prescription Drug Benefit Manual for guidance related to manufacturer patient assistance programs.

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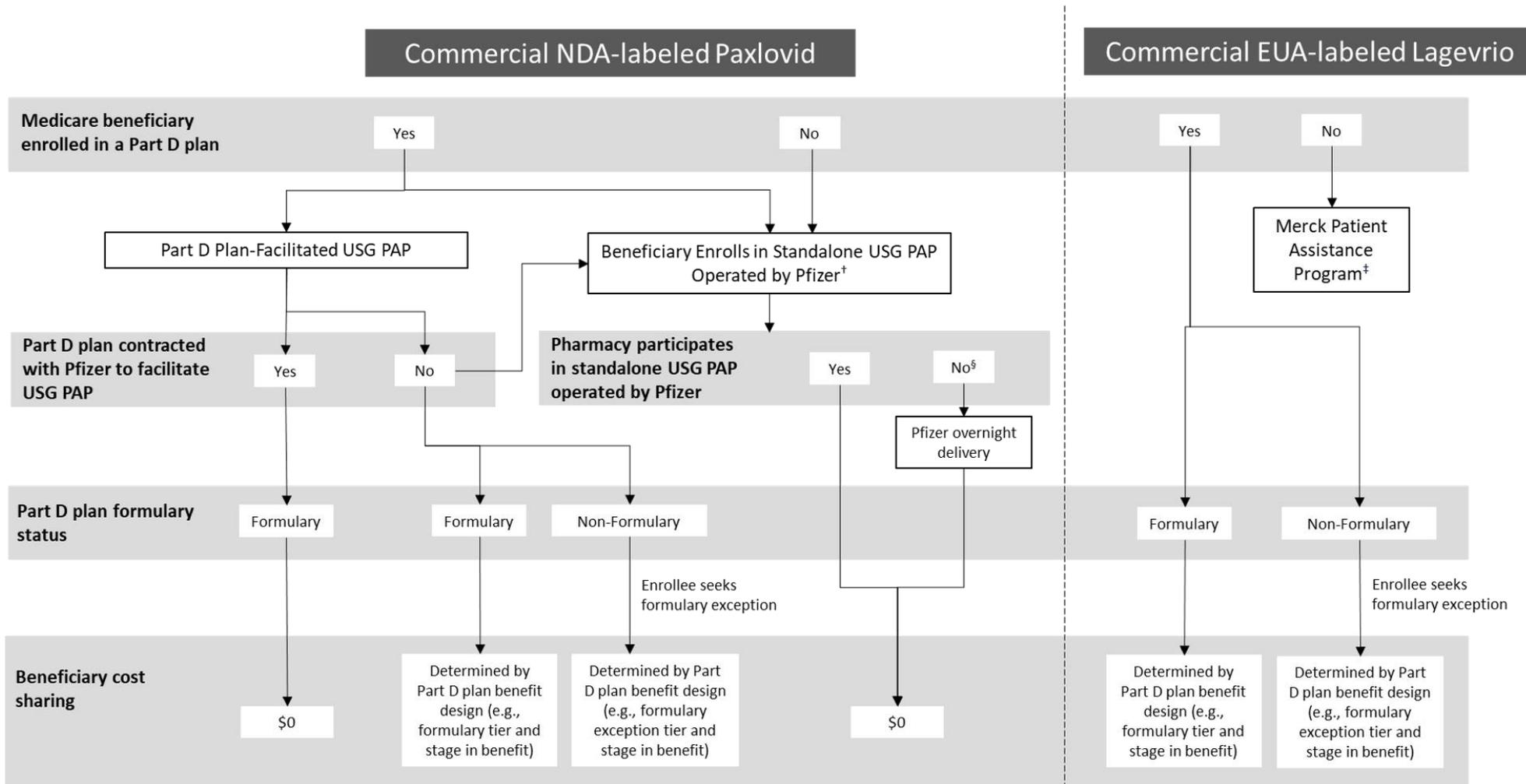
<sup>18</sup> <https://www.merckhelps.com/LAGEVRIO>

### *Summary and Questions*

Figure 1 provides a high-level summary of the primary coverage pathways for oral antivirals for COVID-19 for Medicare beneficiaries.

Please direct questions regarding this guidance to Part D Policy at [PartDPolicy@cms.hhs.gov](mailto:PartDPolicy@cms.hhs.gov), questions regarding PDE reporting to [PDE-Operations@cms.hhs.gov](mailto:PDE-Operations@cms.hhs.gov), questions regarding DIR reporting to [DIR\\_Reporting\\_Reqs@cms.hhs.gov](mailto:DIR_Reporting_Reqs@cms.hhs.gov), and questions on coverage determination processes to <https://appeals.lmi.org/dapmailbox>.

Figure 1. Primary Medicare Beneficiary Coverage Pathways for Commercial Oral Antivirals for COVID-19. Scenarios are presented for illustrative purposes. This is not an exhaustive list of all potential pathways.



<sup>†</sup>Beneficiaries who decline to enroll in the standalone USG PAP operated by Pfizer must obtain coverage for Paxlovid through their Part D plan, if enrolled in one, or pay the full cost of Paxlovid.

<sup>§</sup>Beneficiaries who enroll in the standalone USG PAP operated by Pfizer but cannot locate a pharmacy participating in the standalone USG PAP operated by Pfizer and cannot wait for overnight delivery, must obtain coverage through their Part D plan, if enrolled in one, or pay the full cost of Paxlovid.

<sup>‡</sup> Merck patient assistance program is generally for the uninsured, but individuals with insurance may qualify if they have special circumstances of financial and medical hardship and their income meets program criteria. See <https://www.merckhelps.com/LAGEVRIO>.

## **Summary of Figure 1**

1. Coverage Pathway for Commercial NDA-labeled Paxlovid
  - a. Is the Medicare beneficiary enrolled in a Part D plan?
    - i. If yes, the beneficiary can obtain coverage for Paxlovid through their Part D plan (see level 1.b.) or by enrolling in the standalone USG PAP operated by Pfizer (see level 1.b.ii.1.).
    - ii. If no, the beneficiary can obtain coverage by enrolling the standalone USG PAP operated by Pfizer
      1. Is the beneficiary's pharmacy participating in the standalone USG PAP operated by Pfizer?
        - a. If yes, the beneficiary's cost sharing is \$0
        - b. If no, the beneficiary can obtain Paxlovid via overnight shipping from Pfizer with \$0 cost sharing. Beneficiaries who enroll in the standalone USG PAP operated by Pfizer but cannot locate a pharmacy participating in the standalone USG PAP operated by Pfizer and cannot wait for overnight delivery, must pay the full cost of Paxlovid.
  - b. Is the beneficiary's Part D plan contracted with Pfizer to facilitate the USG PAP?
    - i. If yes, Paxlovid is on the Part D plan formulary and the beneficiary's cost sharing is \$0
    - ii. If no, the beneficiary can either enroll in the standalone USG PAP operated by Pfizer (see level 1.b.ii.1.) or obtain coverage through their Part D plan (see level 1.b.ii.2.).
      1. If the beneficiary enrolls in the standalone USG PAP operated by Pfizer:
        - a. Is the beneficiary's pharmacy participating in the standalone USG PAP operated by Pfizer?
          - i. If yes, the beneficiary's cost sharing is \$0
          - ii. If no, beneficiary can obtain Paxlovid via overnight shipping from Pfizer with \$0 cost sharing. Beneficiaries who enroll in the standalone USG PAP operated by Pfizer but cannot locate a pharmacy participating in the standalone USG PAP operated by Pfizer and cannot wait for overnight delivery, must obtain coverage through their Part D plan or pay the full cost of Paxlovid.
      2. If the beneficiary obtains coverage through their Part D plan:
        - a. If Paxlovid is on the formulary, the beneficiary cost sharing is determined by the Part D plan benefit design (e.g., formulary tier and stage in benefit)
        - b. If Paxlovid is non-formulary, the beneficiary can seek a formulary exception, and the beneficiary's cost sharing is determined by the Part D plan benefit design (e.g., formulary exception tier and stage in benefit)
2. Coverage Pathway for Commercial EUA-labeled Lagevrio
  - a. Is the Medicare beneficiary enrolled in a Part D plan?
    - i. If yes, the beneficiary can obtain coverage for Lagevrio through their Part D plan
      1. If Lagevrio is on the formulary, the beneficiary's cost sharing is determined by the Part D plan benefit design (e.g., formulary tier and stage in benefit)

2. If Lagevrio is non-formulary, the beneficiary can seek a formulary exception, and the beneficiary cost sharing is determined by the Part D plan benefit design (e.g., formulary exception tier and stage in benefit)
- ii. If no, the beneficiary can apply for the Merck patient assistance program. The Merck patient assistance program is generally for the uninsured, but individuals with insurance may qualify if they have special circumstances of financial and medical hardship and their income meets program criteria. See <https://www.merckhelps.com/LAGEVRIO>.