

November 2, 2021

[Sent electronically]
Dr. Meredith Chuk
Office of the Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Chuk,

On September 13, 2021, the Secretary of Health and Human Services, with the support of the Assistant Secretary for Preparedness and Response, authorized pharmacists to order and administer treatments for COVID-19. This authority has been effective to increase patient access to monoclonal antibodies. Unfortunately, a bureaucratic barrier will prevent Medicare and Medicaid beneficiaries from accessing oral antivirals for COVID-19 from their pharmacist, when the FDA authorizes those products.

No payment mechanism currently exists for the Medicare program to reimburse pharmacists for patient assessment services necessary to order appropriate COVID-19 treatments. This barrier will undermine patient access to oral antivirals for COVID-19, particularly in rural and medically underserved communities where pharmacists are often the most accessible healthcare providers.

Payment to healthcare providers for patient evaluation and management services are typically separate from the cost of the drug and from reimbursement for dispensing the drug. In the case of oral antivirals for COVID-19, we anticipate that the drug will be provided at no cost to pharmacies. Part D Plans will likely provide pharmacies a standard dispensing fee under the drug benefit (i.e., Medicare Part D), but no payment mechanism is in place to cover pharmacists' clinical services as the healthcare provider evaluating and managing patients receiving these treatments, as authorized by the 9th Amendment of the PREP Act Declaration. Similar to other healthcare providers, pharmacists will need to assess the patient, verify COVID-19 test results or advise on taking a test if one has not been performed, order/prescribe the oral therapeutic if appropriate, and counsel the patient about the drug product. These are clinical services, separate and apart from the work that goes into preparation and dispensing the drug, and counseling when the drug is dispensed. Reimbursement of physicians and non-physician providers for patient evaluation and management is typically provided by the medical benefit (i.e., Medicare Part B) using E/M codes (e.g., 99202-99205 and 99122-99215). Unfortunately, the Medicare program does not currently provide reimbursement to pharmacists under these codes.

To ensure Medicare and Medicaid beneficiaries have appropriate access to oral antivirals for COVID-19, consistent with the intent of the Secretary's PREP Act declaration, we urge HHS and the Centers for Medicare and Medicaid Services (CMS) to allow the Medicare and Medicaid programs to reimburse pharmacists for patient assessment services under the medical benefit (i.e., Medicare Part B).

Recommendation: Use 1135 waiver authority to provide Medicare and Medicaid coverage of pharmacists' patient assessment services authorized under the PREP Act

Section 1135 of the Social Security Act allows CMS to waive Medicare and Medicaid program requirements, including conditions of participation, in order to ensure sufficient healthcare

services are available to beneficiaries during a public health emergency. CMS should use this authority to allow the Medicare and Medicaid programs to reimburse pharmacists, both directly and incident to other providers, for patient assessment services necessary to order and administer COVID-19 therapeutics, consistent with the Secretary's PREP Act declaration. The Agency has previously used this authority to waive provisions of the Social Security Act to allow Medicare to reimburse pharmacists for administration of vaccines to Medicare beneficiaries in skilled nursing facilities.

The following options should be considered to reimburse pharmacists' patient assessment services authorized under the PREP Act:

- Identify existing CPT code(s) for patient assessment services.
 - Some of these are the codes already used to bill for pharmacist services in Medicaid and commercial health plans.
- Petition AMA CPT Editorial Panel for an emergency CPT code for patient assessment services.
- Develop emergency G codes that are reimbursable for pharmacists' patient assessment services to support ordering of COVID-19 therapeutics:
 - GXXXX "Patient assessment by a pharmacist, COVID-19 therapeutic indicated"
 - GXXXX "Patient assessment by a pharmacist, COVID-19 therapeutic not indicated"

We discourage CMS from directing plans to enhance prescription dispensing fees to reimburse pharmacists for patient assessment services. This pathway will likely prove inadequate to pay pharmacists for clinical services. Patient assessment can occur with or without dispensing of a drug product. Upon evaluation of the patient, the drug product may not be appropriate for the patient, or the patient may be referred to a different setting of care. In this case, the pharmacist does not submit a prescription drug claim and has no ability to receive reimbursement for their services. Our organizations seek to clarify if our understanding of these possible pathways is correct.

Furthermore, in the current pharmacy payment environment, dispensing fees related to COVID-19 oral therapeutics under Part D could be clawed back by PBMs, leaving the pharmacy with inadequate reimbursement for time, resources, and efforts with the patient.

Pharmacists are already billing the medical benefit and being reimbursed for administration of vaccines and monoclonal antibodies, however they are not able to be paid for patient assessment services. Clinical evaluation to determine a patient's need of monoclonal antibodies and oral antiviral treatments, whether or not a medication is dispensed, should also be a reimbursable service by a pharmacist through the medical benefit.

The value to public health of the COVID-19 oral antiviral treatments requires timely and broad access. We strongly encourage the government to make participation in the oral antiviral program open to any pharmacy. Such an approach would improve access to needed therapy, particularly for patients in rural and medically underserved areas.

We believe the above recommendation will facilitate temporary Medicare and Medicaid beneficiary access to oral antivirals for COVID-19. To ensure long-term access to pharmacist services for Medicare

beneficiaries, we encourage HHS to work with Congress to authorize pharmacists as providers under the Social Security Act so Medicare can reimburse pharmacists under Part B. This would allow beneficiaries to access authorized pharmacist services without the need for Medicare or Medicaid waivers.

Sincerely,

American Society of Health-System Pharmacists (ASHP)

American Society of Consultant Pharmacists (ASCP)

National Community Pharmacists Association (NCPA)

National Alliance of State Pharmacy Associations (NASPA)

American Pharmacists Association (APhA)

Society of Infectious Disease Pharmacists (SIDP)

College of Psychiatric and Neurologic Pharmacists (CPNP)

American Association of Colleges of Pharmacy (AACP)

Academy of Managed Care Pharmacy (AMCP)