Information for CPESN Pharmacies Regarding COVID-19 Oral Antiviral Therapy

Antiviral Therapy Product Information

Review <u>Fact Sheet for Healthcare Providers</u> for the antiviral therapy that the pharmacy will be dispensing.
- Paxlovid Fact Sheet for Healthcare Providers: Click here
- Molnupiravir Fact Sheet for Healthcare Providers: Click here

Paxlovid Resources:
- **Public Health Emergency (PHE) Webpage for Paxlovid:** Click here
- **Paxlovid Fact Sheet for Patients, Parents, and Caregivers**: English here. Spanish here.
- **FAQ for Paxlovid EUA**: Click here
- **CPESN Resource for Paxlovid-Prescribing for Pharmacists:** Click here.
- **Paxlovid Checklist Tool for Prescribers (non-pharmacist):** Click here.
- **Instructions for Dispensing Paxlovid for Patients identified by prescribers with moderate renal impairment:** Click here.

Molnupiravir Resources:
- **Public Health Emergency (PHE) Webpage for Molnupiravir:** Click here
- **Molnupiravir Fact Sheet for Patients, Parents, and Caregivers**: English here. Spanish here.
- **FAQ for Molnupiravir EUA:** Click here
- **Molnupiravir Checklist Tool for Prescribers**: Click here.
  - A reference for pharmacies. The tool is what prescribers should be following for prescribing.

Responsibilities of Pharmacies (review Paxlovid FDA EUA for pharmacist-prescribing)
- Dispense the oral covid-19 antiviral therapy with a valid prescription from a physician, advanced practice registered nurse, or physician assistant per the FDA EUAs. A pharmacist can prescribe Paxlovid per the FDA EUA.
- Verification of time since symptom onset. Patient needs to start therapy within 5 days of symptom onset.
  - Prescriber is supposed to have fill by date on the prescription or noting on the prescription how many days the patient is into symptom onset.
  - <u>Best Practice</u>: As you let local prescribers know that you have antiviral therapy at the pharmacy, inform them that they'll need to document on the prescription how many days the patient has been experiencing COVID-19 symptoms. This will prevent delay in patient receiving antiviral therapy. Click here to view additional resources that may be helpful.
- Provide **Antiviral Fact Sheet for the Patient** (print out and bag with prescription).
- Provide patient counseling for oral antiviral product being dispensed.
- Provide renal paxlovid or remove tablets if moderate renal impairment for paxlovid (prescriber is responsible for notating renal dosage adjustment on prescription).
- Report adverse events and medication errors to FDA MedWatch.
- Document course inventory and administration numbers in VPoP/HPoP each Tuesday and Thursday by end of day.

Information for CPESN Pharmacies Regarding COVID-19 Oral Antiviral Therapy

Ordering / Delivery

OAV Order Request Deadlines in VPoP/HPoP each week is Tuesdays and Thursdays at 9 a.m. ET. CPESN USA will process orders, similar to the vaccine ordering process, at those times.

- Pharmacy's OAV inventory and daily reporting requirement compliance will be taken into account for processing orders.
- A pharmacy should not place an order for paxlovid or molnupiravir until the pharmacy has less than 10 courses of the product planned for ordering.

ABC is the distributor of the product. FedEx is the carrier for delivery.

Orders placed by Tuesdays should arrive by Thursday or Friday.

Orders placed by Thursdays should arrive by Tuesday or Wednesday.

VPoP Order Status Descriptions:
- **Completed**: Order has been submitted by CPESN Staff
- **On-hold**: Order that has been completed but provider does not have an AmerisourceBergen (ASD) Account listed in the system. These orders are flagged by ASD and they will review and update the ASD account number. After updating the ASD account number, the order status will change to Distributed/Transmitted. On-hold status should not be > 24-48 hours. The pharmacy or CPESN has no control of this process.
- **Distributed**: Order that has been completed & awaiting ASD to fulfill order in the warehouse.
- **Transmitted**: Order has been downloaded by ASD (the distributor). Orders with this status will be updated to include shipping information when available but note that this shipping data is only updated once a day. After the order is in this status, the pharmacy should receive in 24-48 hours.

Instructions for Inventory/Administration Reporting for # of Courses
If utilizing a different FRPP-Therapeutics partner than CPESN, this may be a different process

The pharmacy is **required** to report COVID-19 antiviral therapy inventory within VPoP each Tuesday and Thursday by end of day. Below is a screenshot of what will appear in your VPoP account.

Instructions: Enter the **courses administered** and **courses available** by clicking the white box and typing in a number value. The column cell appears with a blue corner to indicate unsaved data. Click "Save Therapeutic Courses" and you will see a success message at the top of the page. The History field will automatically update and will contain the previously entered information.
- **Courses available**: courses at the pharmacy available for dispensing at the time of the update
- **Courses administered**: courses administered/dispensed since the last update within VPoP (not cumulative)

Example: On Day 1: The pharmacy receives 24 courses of molnupiravir and enters "0" in **Administered** and "24" in **Available**. On Day 2, the pharmacy dispenses molnupiravir to 5 patients. At

the end of Day 2, enter "5" in **Administered** and "19" **in Available**. By the end of Day 3, the pharmacy dispenses 10 courses. On Day 3, enter "10" in **Administered** and "9" **in Available**. Continue daily.

Click here to view the COVID-19 Therapeutics Locator (updated based on VPoP inventory)

Required Reporting for Serious Adverse Events and Medication Errors:
Review the Fact Sheet for a list of serious adverse events
Submit adverse event and medication error reports, using Form 3500, to **FDA MedWatch** using one of the following methods:
1. Complete and submit the report online: Click here.
2. Complete and submit a postage-paid FDA Form 3500 (click here) and return by:
   Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or Fax to 1-800-FDA-0178.
3. Call 1-800-FDA-1088 to request a reporting form.

Additional steps for each product for reporting serious adverse events and medication errors:
Molnupiravir
- In addition, please provide a copy of all FDA MedWatch forms to:
  Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA Fax: 215-616-5677
  E-mail: dpoc.usa@msd.com
Paxlovid
- In addition, please provide a copy of all FDA MedWatch forms to Pfizer: www.pfizersafetyreporting.com ; Fax #: 1-866-635-8337; Telephone #: 1-800-438-1985

Information for CPESN Pharmacies Regarding COVID-19 Oral Antiviral Therapy

Claim Processing (NCPA Guide with additional details: Click here):

Ingredient cost for the free product should be submitted as $0.00.

- NOTE: Some systems may not be able to successfully exchange the value of $0.00. Trading partners should clearly communicate in advance when alternative values such as $0.01 and/or another value for Basis of Cost Determination (423-DN) are necessary for claims adjudication.

Basis of Cost Determination should be submitted with the value "15" (Free product at no associated cost).

Dispensing Fee: Submit what the default is within the dispensing system.
Enhanced Dispensing Fee: Submit Professional Service Code value of "PE" – Patient Education. Submit an incentive amount for this service. Not all payers may pay but you should submit for this code. We do not expect for payers to pay more than $40 for the enhanced dispensing fee, if it is covered for the plan.

Within the therapeutics/antivirals provider agreement the following requirement is listed (click here for agreement preview). **Pharmacies cannot collect any cost-sharing amount from a patient that is a result of billing dispensing fees for the COVID-19 Oral Antiviral Product.**

- *Organization must dispense COVID-19 therapeutics regardless of the therapeutic recipient's coverage status or ability to pay for COVID-19 therapeutics dispensing fees. Organization may seek appropriate reimbursement from a program or plan that covers COVID-19 therapeutics dispensing fees for the therapeutics recipient. Organization may not seek any reimbursement, including through balance billing, from the therapeutic recipient. Organization may not charge an office visit or other fee if dispensing of the COVID-19 therapeutic is the sole medical service provided. Organization may not require additional unrelated medical or other services or purchases as a condition precedent to receive the COVID-19 therapeutic.*