Billing Guidance for Pharmacy Providers on COVID-19 Oral Antivirals

January 6, 2022

The Department of Health Care Services (DHCS) is providing the following guidance for pharmacy providers regarding the billing of self-administered free COVID-19 oral antiviral drugs, Paxlovid and Molnupiravir.

On December 22, 2021, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the unapproved drug Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use). Paxlovid is a SARS-CoV-2 protease inhibitor antiviral authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. It is given within 5 days of symptom onset. The dosage for Paxlovid is 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together orally twice daily for 5 days.

On December 23, 2021, the FDA issued a EUA for the unapproved drug Molnupiravir.

Molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis. It is authorized for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. It is given as soon as possible after a diagnosis of COVID-19 has been made and within 5 days of symptom onset. The dosage in adult patients is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days.

Providers to note that for Federally Qualified Health Centers (FQHCs) that carve pharmacy into their Prospective Payment System (PPS), the claims would not be separately reimbursed. For
FQHCs that carve out pharmacy benefit, claims would be billed under their pharmacy reimbursement.

**Important Billing Instructions**

- DHCS will follow Center for Medicare & Medicaid Services guidelines for the reimbursement of COVID-19 oral antivirals when administered in accordance with FDA EUA.
- Since the initial supply of the oral antivirals are purchased by the federal government and distributed free to providers, the providers will not be reimbursed the ingredient cost.
- DHCS is currently reimbursing for only the professional dispensing fee. This will be based on a pharmacy’s total (Medicaid and non-Medicaid) annual prescription volume from the previous year as follows:
  - Less than 90,000 claims equal $13.20
  - 90,000 or more claims equal $10.05
- All claims should be submitted to Medi-Cal Rx for processing.
- No prior authorization would be required. The Code 1 restrictions are as follows:
  - Nirmatrelvir/Ritonavir: “Restricted to 30 tablets per dispensing”
  - Molnupiravir: “Restricted to 40 capsules per dispensing”
- DHCS will provide future guidance for the billing and reimbursement of provider-purchased COVID-19 oral antivirals at the appropriate time.
- It is important to provide medication recipients with the EUA fact sheet for patients, parents, and caregivers in accordance with the EUA requirements.

The guidance contained in this directive is only effective for Paxlovid and Molnupiravir purchased by the federal government. DHCS will provide future guidance on the end date of this policy for the reimbursement of provider-purchased medications.

Pharmacy providers may bill for the dispensing of Paxlovid and Molnupiravir National Drug Codes (NDCs) using National Council for Prescription Drug Programs (NCPDP) D.0 claims, web, batch, and paper claims according to the table below.
<table>
<thead>
<tr>
<th>NDC</th>
<th>Label_Name</th>
<th>Generic_Name</th>
<th>Description</th>
<th>Max Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>00069108530</td>
<td>PAXLOVID CO-PACK (EUA)</td>
<td>Nirmatrelvir; Ritonavir</td>
<td>1 box of 30 (outer NDC)</td>
<td>30 tablets</td>
</tr>
<tr>
<td>00069108506</td>
<td>PAXLOVID CO-PACK (EUA)</td>
<td>Nirmatrelvir; Ritonavir</td>
<td>1 blister pack of 6 (Inner NDC)</td>
<td>30 tablets</td>
</tr>
<tr>
<td>00006505506</td>
<td>MOLNUPIRAVIR 200 MG CAP (EUA)</td>
<td>Molnupiravir</td>
<td>1 bottle of 40</td>
<td>40 capsules</td>
</tr>
<tr>
<td>00006505507</td>
<td>N/A</td>
<td>Molnupiravir</td>
<td>1 bottle of 40</td>
<td>40 capsules</td>
</tr>
</tbody>
</table>

**Billing Guidance for Electronic Billing Formats**

To be reimbursed for the professional dispensing fee on the electronic claim formats (NCPDP D.0, web, or batch), pharmacy providers must submit the claim with the appropriate NDC and the billing quantity as shown above.

Pharmacy providers must bill the claim using a transaction Code (103-A3) of “B1” (Claim Billing) with the Basis of Cost Determination value “15” (free product or no associated cost), with an associated Ingredient Cost Submitted (409-D9) value of $0.00, when the pharmacist dispenses the COVID-19 antivirals.

**Billing Guidance for Paper Claim Submission**

To be reimbursed for the administration fee when billing on a paper claim (Pharmacy Claim Form [30-1] or Universal Claim Form), pharmacy providers must submit the claim with the NDC and the billing quantity as identified in the table above.

For population of claim form fields other than those identified in this guidance, please review the Medi-Cal Rx Provider Manual.

Any concerns regarding delay in reimbursement should not cause providers to decline dispensing Paxlovid or Molnupiravir to patients.

Providers with questions should contact the Medi-Cal Rx Customer Service Center at 1-800-977-2273. Representatives are available 24 hours a day, 7 days a week, 365 days per year.

For more information on services covered by Medi-Cal Rx, providers should refer to the Medi-Cal Rx Web Portal.