Provider Playbook: COVID-19 Outpatient Therapeutics

March 2022
The policies outlined in this playbook should be regarded as guidance provided by the National Institute of Health (NIH), Food and Drug Administration (FDA), and the North Carolina Department of Health and Human Services (NC DHHS). This playbook does not cover every clinical scenario and providers should employ clinical decision making as allowed by their licensure scope of practice.

This playbook covers outpatient COVID-19 treatment options available in the state of North Carolina and associated provider guidance and responsibilities necessary to provide COVID-19 therapies.
CONTENT LAYOUT

Additional Links and Resources

**Therapeutics FAQs**
Reference this [site](#) for FAQs regarding COVID-19 mAbs, oral antivirals, treatment, and other questions

**NC Provider Office Hours**
Attend weekly Teams meetings on Fridays at 12pm for questions regarding therapeutic products and the ordering and allocation process (meeting invite link provided in Therapeutics Newsletter)

**Therapeutics Inbox**
Email the NC DHHS COVID-19 Therapeutics Inbox ([Therapeutics.COVID19@dhhs.nc.gov](mailto:Therapeutics.COVID19@dhhs.nc.gov)) for urgent issues
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Please refer to this key throughout to find relevant information:
Monoclonal Antibodies
Antivirals
All COVID-19 Treatment Options
REGEN-COV

Please note: treatment is not authorized for use at this time due to the markedly reduced activity against the Omicron variant

- Manufactured by: Regeneron
- Authorized dosage for REGEN-COV for both treatment and as post-exposure prophylaxis is 600 mg of casirivimab and 600 mg of imdevimab administered together
- REGEN-COV is authorized for patients aged 12 and over
- For treatment, IV infusion is recommended
- Subcutaneous injection (shots administered underneath the skin) is an alternative route of administration when IV infusion is not feasible and would lead to delay in treatment
- For post-exposure prophylaxis, either intravenous infusion or subcutaneous injection is appropriate
- Providers should clinically monitor patients for at least one hour following the infusion/injection for reactions
- Mixing and Dosing Instructions (linked)
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

Bamlanivimab/Etesevimab

Please note: treatment is not authorized for use at this time due to the markedly reduced activity against the Omicron variant

- Manufactured by: Eli Lilly
- Authorized dosage for Bam/Ete for treatment is 700 mg of bamlanivimab and 1400 mg of etesevimab administered together
- Treatment can only be administered through an IV infusion of bamlanivimab and etesevimab as a single intravenous infusion via pump or gravity
- For post-exposure prophylaxis, use the same dosage as treatment and administer through IV infusion
- Authorized for post-exposure prophylaxis and treatment in all younger pediatric patients, including newborns
- The IV infusion will take 21-60+ minutes, dependent upon the providers’ discretion
- Providers should clinically monitor patients for at least one hour after infusion is complete for reactions
- Mixing and Dosing Instructions (linked)
- Visit the Health Care Provider Fact Sheet for further provider guidance and information
## Sotrovimab
- Manufactured by: GlaxoSmithKline
- Authorized dosage for sotrovimab for treatment is 500 mg of sotrovimab
- Sotrovimab is authorized for patients aged 12 and over
- Treatment can only be administered through IV infusion
- The IV infusion should administer the entire bag of solution over 30 minutes when using a 100mL infusion bag, or should be adjusted to 15 minutes when using a 50mL infusion bag
- Providers should clinically monitor patients for at least one hour after infusion is complete for reactions
  - [Mixing and Dosing Instructions](#) (linked)
- Visit the [Health Care Provider Fact Sheet](#) for further provider guidance and information

## Bebtelovimab
- Manufactured by: Eli Lilly and Company
- Authorized dosage for bebtelovimab for treatment is 175 mg of bebtelovimab
- Bebtelovimab is approved in adults and pediatric patients (12 years of age and older and weighing at least 40 kg)
- Bebtelovimab can only be delivered as a single intravenous injection over at least 30 seconds
- Bebtelovimab is approved for treatment in patients with a positive COVID-19 test who are at high risk for progression to severe COVID-19, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate (VEKLURY is not considered an authorized alternative option)
- Providers should clinically monitor patients for at least one hour after infusion is complete for reactions
- Visit the [Health Care Provider Fact Sheet](#) for further provider guidance and information

## EVUSHELD
- Manufactured: AstraZeneca
- Authorized dosage for EVUSHELD, formerly known as AZD7442, is a combination of two LAABs for pre-exposure prevention as 300 mg of tixagevimab and 300 mg of cilgavimab administered in two separate, consecutive injections
- EVUSHELD is approved for adults and adolescents with moderate to severe immune compromise who may not mount an adequate immune response to COVID-19 vaccinations
- EVUSHELD can only be delivered as an intramuscular dose
- EVUSHELD is not yet approved for COVID-19 prophylaxis and treatment
- Patients who have already received the previously authorized dose should receive an additional dose of 150 mg as soon as possible Providers should clinically monitor patients for at least one hour following the injection for reactions
- Timing for receiving additional doses of EVUSHELD, beyond the initial 600 mg, is still being studied
- Visit the [Health Care Provider Fact Sheet](#) for further provider guidance and information
<table>
<thead>
<tr>
<th>PRODUCT SPECIFICATIONS (3 OF 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PAXLOVID</strong></td>
</tr>
<tr>
<td>• Manufactured by: Pfizer</td>
</tr>
<tr>
<td>• Authorized dosage for PAXLOVID is a combination of 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, with or without food</td>
</tr>
<tr>
<td>• Dosage adjustment required for moderate renal impairment (eGFR ≥30 to &lt;60 mL/min)</td>
</tr>
<tr>
<td>• PAXLOVID is approved for adults and pediatric patients (age 12 and older)</td>
</tr>
<tr>
<td>• PAXLOVID can only be delivered as an oral pill</td>
</tr>
<tr>
<td>• PAXLOVID is approved for treatment in patients with a positive COVID-19 test who are at high risk for progression to severe COVID-19</td>
</tr>
<tr>
<td>• Providers should monitor patients with potential drug interactions for adverse reactions</td>
</tr>
<tr>
<td>• Visit the Health Care Provider Fact Sheet for further provider guidance and information</td>
</tr>
</tbody>
</table>

| **Molnupiravir**              |
| • Manufactured by: Merck      |
| • Authorized dosage for molnupiravir is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food |
| • Molnupiravir is only approved for adults |
| • Molnupiravir can only be delivered as an oral pill |
| • Molnupiravir is approved for treatment in patients with a positive COVID-19 test who are at high risk for progression to severe COVID-19, and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate |
| • Providers should monitor patients with potential drug interactions for adverse reactions |
| • Visit the Health Care Provider Fact Sheet for further provider guidance and information |

| **VEKLURY (remdesivir)**      |
| • Manufactured: Gilead Sciences, Inc. |
| • Authorized dosage for VEKLURY varies, please refer to the dosage guidance [here](#) |
| • VEKLURY is a drug approved for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are: Hospitalized, or Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. |
| • VEKLURY can only be delivered as an intravenous (IV) infusion |
| • Providers should clinically monitor patients for at least one hour following the infusion for reactions |
| • Visit the Health Care Provider Fact Sheet for further provider guidance and information |
mAbs Treatment
MONOCLONAL ANTIBODIES – OVERVIEW (1 OF 2)

Please note: REGEN-COV and Bam/Ete are not authorized for use at this time due to their markedly reduced activity against the Omicron variant.

Monoclonal antibodies, or mAbs, are antibodies made in a laboratory to fight a particular infection. The Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the use of monoclonal antibody therapies for adult and pediatric patients aged 12 and older (Bam/Ete authorized for all ages). mAbs are given to patients with an infusion, subcutaneous injection, or intramuscular injection. They are used for treatment or prevention. There are four mAbs products currently authorized for use for COVID-19:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Also known as</th>
<th>Authorized Indication</th>
<th>Route of Administration</th>
<th>Dosing Regimen</th>
<th>Authorized Patient Population</th>
<th>Standing Order*</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casirivimab / imdevimab</td>
<td>REGEN-COV</td>
<td>Post-exposure Prophylaxis, Treatment within 10 days of symptoms</td>
<td>Subcutaneous Injection; Intravenous Infusion</td>
<td>600 mg of both</td>
<td>Patients aged 12 years and older</td>
<td>No, rescinded January 24th</td>
<td>70% effective in preventing hospitalizations or deaths within five (5) days of symptom onset</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Reduced efficacy against Omicron</td>
</tr>
<tr>
<td>Bamlanivimab / etesevimab</td>
<td>Bam/Ete</td>
<td>Post-exposure Prophylaxis, Treatment within 10 days of symptoms</td>
<td>Intravenous Infusion</td>
<td>Dosage varies with weight</td>
<td>Patients of all ages, including neonates</td>
<td>No, rescinded January 24th</td>
<td>87% effective in preventing hospitalizations or deaths within five (5) days of symptom onset</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Reduced efficacy against Omicron</td>
</tr>
</tbody>
</table>

*Per the Public Readiness and Emergency Preparedness Act, pharmacies were added to the eligible providers and can now administer monoclonal antibody treatment.
**MONOCLONAL ANTIBODIES – OVERVIEW (2 OF 2)**

Monoclonal antibodies, or mAbs, are antibodies made in a laboratory to fight a particular infection. The Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the use of monoclonal antibody therapies for adult and pediatric patients aged 12 and older. mAbs are given to patients with an infusion, subcutaneous injection, or intramuscular injection. They are used for treatment or prevention. There are three mAb products currently authorized for use that are effective against currently circulating SARS-CoV-2 variants:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Also known as</th>
<th>Authorized Indication</th>
<th>Route of Administration</th>
<th>Dosing Regimen</th>
<th>Authorized Patient Population</th>
<th>Standing Order?*</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sotrovimab</td>
<td>Sotrovimab</td>
<td>COVID-19 Treatment within seven (7) days of symptoms</td>
<td>Intravenous Infusion</td>
<td>500 mg of sotrovimab</td>
<td>Patients aged <strong>12 years and older</strong> and weighing at least 40 kg</td>
<td>Yes, revised February 15th</td>
<td><strong>79% effective</strong> in preventing hospitalizations or death. Retains efficacy against Omicron. In-vitro data suggests some reduced efficacy against BA.2 subvariant. Clinical impacts unknown at this time</td>
</tr>
<tr>
<td>Bebtelovimab</td>
<td>Bebtelovimab</td>
<td>COVID-19 Treatment within seven (7) days of symptoms</td>
<td>Intravenous Infusion</td>
<td>175 mg of bebtelovimab</td>
<td>Patients aged <strong>12 years and older</strong> and weighing at least 40 kg</td>
<td>Yes, as of February 15th</td>
<td>Placebo controlled trial data not available to determine % effectiveness at reducing hospitalization. Retains efficacy against Omicron and the BA.2 Omicron subvariant</td>
</tr>
<tr>
<td>Tixagevimab / cilgavimab</td>
<td>EVUSHELD AZD7442</td>
<td>Pre-exposure prophylaxis (PrEP)</td>
<td>Intramuscular Injection</td>
<td>300 mg of tixagevimab and 300 mg of cilgavimab</td>
<td>Patients aged <strong>12 years and older</strong> who are immunocompromised or have a contraindication for COVID-19 vaccines</td>
<td>No – per FDA/HHS</td>
<td><strong>77% effective</strong> in preventing SARS-CoV-2 RT-PCR symptomatic illness. Higher dose may be more likely to prevent infection by the COVID-19 Omicron subvariants BA.1 and BA.1.1</td>
</tr>
</tbody>
</table>

*Per the Public Readiness and Emergency Preparedness Act, pharmacies were added to the eligible providers and can now administer monoclonal antibody treatment*
Antiviral Treatments
ORAL ANTIVIRALS - OVERVIEW

The FDA has issued EUAs for the use of oral antiviral therapies for adult and pediatric patients aged 12 and older (molnupiravir authorized for 18+ only). Oral antivirals are administered orally and only used for treatment. There are two (2) types of oral antivirals that have been authorized for use for COVID-19. Both therapeutics target mild-to-moderate COVID-19 for adults who are at risk of severe illness:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Also known as</th>
<th>Authorized Indication</th>
<th>Route of Administration</th>
<th>Administration Requirements</th>
<th>Dosing Regimen</th>
<th>Authorized Patient Population</th>
<th>Standing Order?</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molnupiravir</td>
<td>MK-4482, Merck</td>
<td>Treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and for whom alternate treatment is not accessible or clinically appropriate</td>
<td>Oral</td>
<td>Must start within five (5) days of symptom onset</td>
<td>800 mg twice-daily for five (5) days</td>
<td>Adult patients aged 18 years and older</td>
<td>No – per FDA/HHS</td>
<td>30% effective in preventing hospitalizations or deaths within five (5) days of symptom onset</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not recommended during pregnancy</td>
<td></td>
<td></td>
<td></td>
<td>Retains efficacy against Omicron</td>
</tr>
<tr>
<td>Paxlovid</td>
<td>Nirmatrelvir / Ritonavir, Pfizer</td>
<td>Treatment of mild-to-moderate COVID-19 in adult and pediatric patients (12+) who are at risk for progressing to severe COVID-19</td>
<td>Oral</td>
<td>Must start within five (5) days of symptom onset</td>
<td>300 mg of nirmatrelvir and 100 mg of ritonavir twice-daily for five (5) days</td>
<td>Patients aged 12 years and older</td>
<td>No – per FDA/HHS</td>
<td>88% effective in preventing hospitalizations or deaths within five (5) days of symptom onset</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dosage adjustment required for moderate renal impairment (eGFR ≥30 to &lt;60 mL/min)</td>
<td></td>
<td></td>
<td></td>
<td>Expected to maintain effectiveness across all variants</td>
</tr>
</tbody>
</table>

- EUA: Emergency Use Authorization
- eGFR: Estimated Glomerular Filtration Rate
- FDA/HHS: U.S. Food and Drug Administration/Health and Human Services

**Molnupiravir (MK-4482, Merck)**
- **Authorized Indication:** Treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and for whom alternate treatment is not accessible or clinically appropriate.
- **Route of Administration:** Oral
- **Administration Requirements:** Must start within five (5) days of symptom onset. Not recommended during pregnancy.
- **Dosing Regimen:** 800 mg twice-daily for five (5) days.
- **Authorized Patient Population:** Adult patients aged 18 years and older.
- **Standing Order:** No – per FDA/HHS.
- **Efficacy:** 30% effective in preventing hospitalizations or deaths within five (5) days of symptom onset. Retains efficacy against Omicron.

**Paxlovid (Nirmatrelvir / Ritonavir, Pfizer)**
- **Authorized Indication:** Treatment of mild-to-moderate COVID-19 in adult and pediatric patients (12+) who are at risk for progressing to severe COVID-19.
- **Route of Administration:** Oral
- **Administration Requirements:** Must start within five (5) days of symptom onset. Dosage adjustment required for moderate renal impairment (eGFR ≥30 to <60 mL/min).
- **Dosing Regimen:** 300 mg of nirmatrelvir and 100 mg of ritonavir twice-daily for five (5) days.
- **Authorized Patient Population:** Patients aged 12 years and older.
- **Standing Order:** No – per FDA/HHS.
- **Efficacy:** 88% effective in preventing hospitalizations or deaths within five (5) days of symptom onset. Expected to maintain effectiveness across all variants.
VEKLURY (REMDESIVIR) - OVERVIEW

Please Note: VEKLURY (remdesivir) is not allocated by the federal government and only available commercially.

Veklury is an antiviral medication that works by inhibiting an enzyme that is essential for SARS-CoV-2 viral replication. The FDA has granted full approval for treatment in both hospitalized and non-hospitalized patients who are 12 years of age or older. The FDA has also issued an EUA for treatment in both hospitalized and non-hospitalized patients less than 12 years of age.


<table>
<thead>
<tr>
<th>Generic Name</th>
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<th>Authorized Patient Population</th>
<th>Standing Order?</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remdesivir</td>
<td>VEKLURY</td>
<td><strong>Full FDA Approval</strong></td>
<td>Intravenous Infusion</td>
<td>May only be administered in settings in which healthcare providers have immediate access to medications to treat severe infusion or hypersensitivity reactions and the ability to activate EMS</td>
<td>For patients weighing 40kg or greater: 200mg loading dose on Day 1, followed by a once-daily maintenance dose of 100mg from Day 2</td>
<td>Full FDA Approval Adults and pediatric patients (aged 12 years and older and weighing at least 40 kg)</td>
<td>No</td>
<td>87% effective at preventing hospitalization/death compared to placebo in non-hospitalized patients considered at high-risk for progression to severe COVID-19</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>EUA</strong></td>
<td></td>
<td></td>
<td>For patients weighing less than 40kg: 5mg/kg loading dose on Day 1, followed by a once-daily maintenance dose of 2.5mg/kg from Day 2</td>
<td>EUA Pediatric patients aged 12 years and older weighing 3.5kg to less than 40kg, or pediatric patients less than 12 years of age weighing at least 3.5kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Full FDA Approval</strong></td>
<td></td>
<td></td>
<td><strong>Treatment duration:</strong> Hospitalized patients - 5-10 days total, Non-hospitalized patients – three (3) days total</td>
<td></td>
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</tbody>
</table>

Remdesivir, also known as VEKLURY, is approved for treatment of COVID-19 for adult and pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19.

EUA is approved for treatment of COVID-19 for pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19.

Remdesivir retains efficacy against Omicron.
Treatment Prioritization
PRIORITIZATION OF COVID-19 THERAPEUTICS

Due to lessening supply constraints, NCDHHS has removed its recommendation for patient prioritization to Tier 1, Tier 2 and Tier 3 (referenced below) of the National Institutes of Health (NIH) Guidelines Panel Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies. This expands patient eligibility to that authorized through the FDA Emergency Use Authorization for each individual product.

The North Carolina Standing Order for Sotrovimab has been updated to reflect this removal of prioritization criteria and can be viewed [here](#). Additionally, NCDHHS has issued a North Carolina Standing Order for Bebtelovimab that can be viewed [here](#).

NCDHHS is continuously monitoring supply of all COVID-19 therapeutics and will update these recommendations on patient prioritization, as necessary.

<table>
<thead>
<tr>
<th>Tier</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>• Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors)</td>
</tr>
<tr>
<td>Tier 2</td>
<td>• Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged &lt;65 years with clinical risk factors)</td>
</tr>
<tr>
<td>Tier 3</td>
<td>• Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors)</td>
</tr>
</tbody>
</table>
ALL TREATMENT PRODUCTS PRIORITIZATION

Treatment Products

For non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression, the NIH Panel recommends using one (1) of the following therapeutics (listed in order of preference):

1. PAXLOVID
2. Sotrovimab
3. Remdesivir*

If none of the preferred therapies for high-risk, non-hospitalized patients are available, feasible to deliver, or clinically appropriate (e.g., due to drug-drug interactions, concerns related to renal or hepatic function), the Panel recommends using 1 of the following therapies (listed in alphabetical order):

1. Bebtelovimab
2. Molnupiravir

Note: At this time, REGEN-COV and bamlanivimab and etesevimab are no longer authorized for use due to available data that shows these products are not effective against the Omicron variant.

*Remdesivir is not allocated by the federal government and is only available for private purchase
COVID-19 Outpatient Therapeutics
Clinical Decision Aid for Ages 12+

Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease

Is patient hospitalized for COVID-19?

- Yes
  - Does patient have severe renal impairment (eGFR <30 mL/min) or severe hepatic impairment (Child-Pugh Class C)?
    - Yes, consider sotrovimab
      - 500 mg IV begun ASAP within 7 days of symptom onset
    - No, consider molnupiravir
      - 800 mg by mouth every 12h for 5 days begun ASAP within 7 days of symptom onset
  - No, consider bebtelovimab
    - 175 mg single IV injection ASAP within 7 days of symptom onset

Is patient age 18 or older AND possibility of pregnancy, if applicable, ruled out?

- Yes, consider molnupiravir
  - 800 mg by mouth every 12h for 5 days begun ASAP within 7 days of symptom onset
- No, consider bebtelovimab
  - 175 mg single IV injection ASAP within 7 days of symptom onset

References:
2 Drug Interactions Between Ritonavir & Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications. https://www.covid19treatmentguidelines.nih.gov/therapies/statement
3 Consider molnupiravir 800 mg by mouth every 12h for 5 days begun ASAP within 7 days of symptom onset
4 Prescribers must review and comply with the mandatory requirements outlined in the molnupiravir EUA
5 For none of these therapeutics are available, feasible to deliver, or clinically appropriate for patient treatment.
Clinical Decision Aid for Pediatric Patients

Outpatient 3.5 kg to less than 40 kg or younger than 12 years of age weighing at least 3.5 kg, with mild to moderate COVID-19 and at high risk for progression to severe disease

- Symptom onset within the past 7 days?
  - YES
  - Pediatric patient (greater than 28 days old) with severe renal impairment (eGFR <30 mL/min)
  - OR
  - Full-term neonate (7 to 28 days old) with serum creatinine greater than or equal to 1 mg/dL?
  - YES
    - Treatment of symptoms, management per NIH & CDC Guidelines
  - NO
    - Consider Veklury (remdesivir)* begun ASAP within 7 days of symptom onset
      - Pediatric patients younger than 12 years and weighing 40 kg or greater: 200 mg IV x 1 dose on Day 1, 100 mg IV x 1 on Days 2–3
      - Pediatric patients 3.5 kg to less than 40 kg or pediatric patients younger than 12 years weighing at least 3.5 kg: 5 mg/kg IV on Day 1, 2.5 mg/kg on Days 2–3

*Use 100 mg lyophilized vial for EUA pediatric use

Reference:
* Remdesivir EUA: https://www.fda.gov/media/137566/download
Registration
NEW PROVIDER REGISTRATION

New providers should register with the state’s COVID-19 treatment program for all COVID-19 therapeutic products by completing NC DHHS Therapeutics New Provider Request Form. NC DHHS will then create your account in the Health Partners Ordering Portal (HPOP) as a registered provider.*

Registration Requirements:
• When your account is created in HPOP, you will receive an email from vpop_no_reply@cdc.gov allowing you complete the enrollment process
• To activate your account, you must verify your site address and receiving hours. You must complete these steps to request allocations

It will take 2-3 business days to process your registration. Registration does not guarantee that you will receive allocation.

For additional guidance please visit the HPOP Provider Portal - Get Started.

*Ordering therapeutics and provider registration has transitioned from the C19 ABC Portal to HPOP as of 14 FEB 22.
Physicians, advanced practice registered nurses, and physician's assistants with active licensure and in good standing with their respective governing bodies can prescribe and dispense oral antivirals for treatment of COVID-19 in accordance with the PAXLOVID and molnupiravir EUAs, from their offices, if the following conditions are met:

1. There is absolutely no charge to the patient for the drug or act of dispensing, including seeking reimbursement of dispensing fees through third-party payors
2. Products are labeled in accordance with State and Federal dispensing laws. Details from the NC Board of Pharmacy on what information must be included on a prescription label can be found here

Physicians who wish to dispense oral antivirals for the treatment of COVID-19 (or any other medication) for a fee must be registered with the NC Board of Pharmacy as a dispensing physician.

Nurse Practitioners and Physician's Assistants who wish to dispense medications other than COVID-19 therapeutics (whether a fee is charged or not) or who wish to dispense COVID-19 therapeutics for a fee must register with the Board of Pharmacy as a nurse practitioner or physician's assistant.

For more information on becoming a dispensing physician, nurse practitioner, or physician's assistant please visit the NC Board of Pharmacy Dispensing Physician, Physician Assistant and Nurse Practitioners Registration Requirements.
Allocation & Site Finder
HOW TO LOCATE COVID-19 THERAPEUTICS

The ‘Information For Individuals at Higher Risk’ section on the NC DHHS website includes a ‘Site Finder’ tool specifically for EVUSHELD treatment locations.

The ‘Find COVID-19 Treatment’ section on the NC DHHS website includes an updated ‘Site Finder’ tool that enables recipients to: 1) Search for nearby treatment sites, 2) Discover available treatments each site offers for administration, 3) Find resources to schedule an appointment (phone numbers, websites).
SITE FINDER REGISTRATION

All providers serving the greater population (excluding long-term care facilities) requesting mAbs or oral antivirals allocations are **required** to be listed on the NC DHHS website so that community members seeking treatment are aware that your facility may be able to serve them. **All providers will be automatically added to the Site Finder upon receiving allocation or reporting administrations.**

To update, delete, or add missing information to your posting on the Site Finder tool, please complete the [Site Finder Provider Information survey](#).

Your location will be listed on the **mAbs and Oral Antivirals Site Finder Tool** and/or the **EVUSHELD Site Finder Tool** embedded on the [NC DHHS website](#). This ensures all eligible recipients can easily and equitably locate, access, and schedule appointments to receive this potentially lifesaving treatment.
UPDATED THERAPEUTICS ALLOCATION RESTRICTIONS

Allocation requests will be denied or reduced if provider locations have more than three (3) weeks of on-hand inventory of the requested product.

If you are denied allocation and have an urgent need for additional product:
- Please first check the [NC COVID-19 Therapeutics Transfer Marketplace](#).
  - If you are unable to find a transfer partner, then please reach out to [therapeutics.COVID19@dhhs.nc.gov](mailto:therapeutics.COVID19@dhhs.nc.gov)
- Once your on-hand inventory is less than your 3-week utilization history, please feel free to re-request additional PRODUCT via the appropriate request form found in the [Provider Hub](#).

Inventory and Administration Tracking Message for Providers
If your current inventory of any product and your 3-week administration total differs from the numbers you have self reported of administrations and inventory to HPOP & the NC Admin/Inventory Report, providers should notify [therapeutics.COVID19@dhhs.nc.gov](mailto:therapeutics.COVID19@dhhs.nc.gov) with the correct numbers so that we may have an accurate reporting to properly assess requests and ensure that product is allocated where it is most needed.
NC DHHS is responsible for the **management and distribution of mAbs treatment allocations** requested by providers within the state.

**To request product:** Complete the [Sotrovimab Allocation Request Survey](#) and/or the [Bebtelovimab Allocation Request Survey](#).

- Providers must be registered in HPOP to request monoclonal antibodies.
- Providers must submit allocation requests by **Mondays, every week at 12pm EST**, to be eligible to receive mAbs shipments. Requests will be processed on Monday afternoons.
- There is not an option to return product to the manufacturer. Please only request the number of courses you can **administer within seven (7) days and hold no more than three (3) weeks of on-hand inventory**. If extra product is available on-hand, please facilitate a transfer with another facility in need of that product.
- Providers should always submit allocation requests in number of courses.

NC DHHS will send order confirmations of allocation request receipts via the Therapeutics Mailbox every Wednesday.
REQUESTING MABS ALLOCATIONS (2 OF 3)

To request and receive shipment, providers must be registered with HPOP. For the current registration process, please refer to slide 18.
NC DHHS reviews all requests to ensure orders align with state ordering guidelines and meet a specific set of criteria.

This criteria is determined by HHS on the number of weekly allocation amounts provided to the state and on the number of requests received by the state from the Allocation Request Forms submitted by providers. State ordering guidelines for mAbs is provided below:

<table>
<thead>
<tr>
<th>mAbs Treatment</th>
<th>Antiviral Treatments</th>
<th>Registration</th>
<th>Allocation &amp; Site Finder</th>
<th>Shipping &amp; Storage</th>
<th>Preparation &amp; Administration</th>
<th>Post-Treatment Monitoring</th>
<th>Reporting &amp; Billing</th>
<th>Governance</th>
</tr>
</thead>
</table>
| **REQUESTING MABS ALLOCATIONS (3 OF 3)**

Sotrovimab (GlaxoSmithKline) | Bebtelovimab (Eli Lilly) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minimum Order Quantity (MOQ)</strong></td>
<td>6</td>
</tr>
<tr>
<td><strong>Maximum Order Request</strong></td>
<td>If requesting &gt; MOQ: Only order enough inventory to meet one (1) week of utilization demand</td>
</tr>
<tr>
<td><strong>Reporting Method</strong></td>
<td>All administrations must be reported via HHS tele-tracking &amp; the State Inventory and Administration Survey</td>
</tr>
<tr>
<td>Reporting mechanisms vary for hospitals</td>
<td></td>
</tr>
<tr>
<td><strong>Direct Ship Available</strong></td>
<td>✔</td>
</tr>
</tbody>
</table>
REQUESTING EVUSHELD ALLOCATION (1 OF 3)

NC DHHS is responsible for the management and distribution of EVUSHELD allocations requested by providers within the state.

To Request product: Complete the EVUSHELD Allocation Request Form.

• Providers can submit allocation requests at any time. Requests will be processed on Mondays, every week at 12pm EST

• There is not an option to return product to the manufacturer. Please only request the number of courses you can administer within seven (7) days and hold no more than three (3) weeks of on-hand inventory. If extra product is available on-hand, please facilitate a transfer with another facility in need of that product

• Providers should always submit allocation requests in number of cartons. As a reminder, the updated initial dose for EVUSHELD requires two cartons of product per patient. A “catch-up” dose of EVUSHELD requires one carton of product

Confirmation of allocation request receipt is distributed from the Therapeutics Mailbox every Tuesday.
To request and receive shipment, providers must be registered within HPOP. For the current registration process, please refer to slide 19.
REQUESTING EVUSHELD ALLOCATIONS (3 OF 3)

NC DHHS reviews all requests to ensure orders align with state ordering guidelines and meet a specific set of criteria.

This criteria is determined by the HHS on the number of weekly allocation amounts provided to the state and on the number of requests received by the state from the Allocation Request Forms submitted by providers. State ordering guidelines for EVUSHELD is provided below:

<table>
<thead>
<tr>
<th>Minimum Order Quantity (MOQ)</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Order Request</td>
<td>If requesting &gt; MOQ: Only order enough inventory to meet one (1) week of utilization demand</td>
</tr>
<tr>
<td>Reporting Method</td>
<td>All administrations must be reported DAILY in cartons via the Health Partner Ordering Portal (HPOP)</td>
</tr>
<tr>
<td>Direct Ship Available</td>
<td>✓</td>
</tr>
</tbody>
</table>
REQUESTING ORAL ANTIVIRALS ALLOCATION (1 OF 3)

NC DHHS is responsible for the management and distribution of oral antivirals treatment allocations requested by providers within the state.

To request product: Complete the PAXLOVID Allocation Request Survey and/or the Molnupiravir Allocation Request Survey.

- Providers must be registered in HPOP to request oral antivirals
- Providers must submit oral antiviral allocation requests by Mondays, every week at 12pm EST to be eligible to receive shipment
- There is not an option to return product to the manufacturer. Please only request the number of courses you can administer within seven (7) days and hold no more than three (3) weeks of on-hand inventory. If extra product is available on-hand, please facilitate a transfer with another facility in need of that product
- Providers should always submit allocation requests in number of courses

Confirmation of allocation request receipt is distributed from the Therapeutics Mailbox every Wednesday.
REQUESTING ORAL ANTIVIRALS ALLOCATIONS (2 OF 3)

To request and receive shipment, providers must be registered within the HPOP. For the current registration process, please refer to slide 19.
REQUESTING ORAL ANTIVIRALS ALLOCATIONS (3 OF 3)

NC DHHS reviews all requests to ensure orders align with state ordering guidelines and meet a specific set of criteria.

This criteria is determined by the HHS on the number of weekly allocation amounts provided to the state and on the number of requests received by the state from the Allocation Request Forms submitted by providers. State ordering guidelines for oral antivirals is provided below:

<table>
<thead>
<tr>
<th>Minimum Order Quantity (MOQ)</th>
<th>Molnupiravir (Merck)</th>
<th>PAXLOVID (Pfizer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

If requesting > MOQ: Only order enough inventory to meet one (1) week of utilization demand

All administrations must be reported via the Health Partner Ordering Portal (HPOP) DAILY when location is open

Direct Ship Available

✅ ✅
Shipping & Storage
SHIPPING & STORAGE

Shipping:
ABC fulfills and ships mAb and oral antiviral product orders. NC DHHS does not control these functions. Visit ABC’s Tracking Tool Website to track order status.

• Use account # provided by ABC
• ABC delivers the drug to the site of care
• The product is shipped refrigerated and must be stored refrigerated
• If request is approved, NC DHHS confirms and enters orders by Friday of the same week. Expected delivery time of orders is the following Tuesday at the latest
• For access and more information regarding ABC shipping, contact customersystemsupport@AmerisourceBergen.com

Storage:

• mAbs: Provider must store product refrigerated at 2° C to 8° C (36° F to 46° F) in the original carton to protect from light before use. Discard any unused portion. DO NOT FREEZE. DO NOT SHAKE
• Oral Antivirals: Store at USP controlled room temperature 20° C to 25° C (68° F to 77° F); excursions permitted between 15° C to 30° C (59° F to 86° F)
Preparation & Administration
MABS PREPARATION & ADMINISTRATION

Upon receipt of mAbs product(s), providers must adhere to the following federal requirements:

1) Administration preparation process:
   • Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies
   • Obtain new vial(s) and/or IV bags if the drug product contains any visible particulate matter

2) Needs for space to prepare mAb drug:
   • Dedicated preparation area, in addition to sufficient administration capacity onsite or nearby

3) Acceptable equipment for mAb drug storage:
   • Refrigerated storage (2-8° C)
   • Temperature control mechanism, including temperature monitoring process

mAbs can be prepared for infusion and subcutaneous administration bedside by any qualified medical professional.

Please see EUA manufacturer fact sheet for drug-specific requirements.
Upon receipt of oral antiviral product(s), providers must adhere to the following requirements:

1) Dosage & administration:

- **Molnupiravir**: The dosage in adult patients is 800 mg (four 200 mg capsules) taken orally every 12 hours for five (5) days, with or without food
  - Take molnupiravir as soon as possible after a diagnosis of COVID-19 has been made, and within five (5) days of symptom onset
  - Completion of the full five-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2
  - Molnupiravir is not authorized for use for longer than five (5) consecutive days because the safety and efficacy have not been established

- **PAXLOVID**: 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 five (5) days, with or without food
  - Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID
  - Completion of the full five-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2
  - Dosage adjustment required for moderate renal impairment (eGFR ≥30 to <60 mL/min). Pharmacists should discard the removed tablets per state requirements or local guidelines. Please refer to the HCP Letter for further information

2) Acceptable equipment for oral antiviral drug storage:

- USP Controlled Room Temperature 20° C to 25° C (68° F to 77° F)
- Excursions permitted between 15° C to 30° C (59° F to 86° F)

Please see EUA manufacturer fact sheet for drug-specific requirements
VACCINATION CONSIDERATIONS

Following updated guidance from the CDC, it is no longer necessary to delay COVID-19 vaccination following receipt of monoclonal antibodies.

People who received passive antibody products

- People who previously received antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment, post-exposure prophylaxis, or pre-exposure prophylaxis can be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma. Although some reduction in vaccine-induced antibody was observed in people who previously received antibody products, the clinical significance of this reduction is unknown, and the balance of benefits vs. risks favors proceeding with vaccination even considering the possibility of diminished vaccine effectiveness in this situation.

- However, in people who previously received a COVID-19 vaccine, administration of tixagevimab/cilgavimab (EVUSHELD) for pre-exposure prophylaxis should be deferred for at least two weeks after vaccination, per the product EUA.

Additional considerations

- Providers should consult treatment guidelines for use of monoclonal antibodies as pre-exposure prophylaxis for moderately or severely immunocompromised people who may not mount an immune response to COVID-19 vaccination.

For more information, please see the CDC's interim vaccine guidelines.
Please be aware that REGEN-COV has multiple packaging types, and it is essential you take note of the differences when administering the product.

Packaging: The REGEN-COV™ may arrive in one of two (2) packaging configurations:

1) REGEN-COV™ Dose Packs (2-Vial) or
2) Casirivimab and Imdevimab Co-Pack (two (2) vials per carton): One Carton allows for preparation of two (2) treatment doses

It is important that providers and those mixing and/ or administering the product pay close attention to the dosage and refer to the QR code enclosed with the product for updates. Please refer to the Labeling and Packaging one pager and Regeneron website for the latest information and instructions for each formulation.

Labeling:

• In addition to the packaging configurations noted above, some REGEN-COV™ carton and vial labels may have statements such as “Solution for Intravenous Administration” or “For Intravenous Infusion after Dilution.”

• Any of these REGEN-COV™ vials may be used to prepare and administer intravenous infusions as well as subcutaneous injections, even though there is no language on the label that that states the subcutaneous route is appropriate.
Post-Treatment Monitoring
POST-TREATMENT PATIENT MONITORING

**mAbs**

1. Provide to and review with the patient: [COVID-19 Antibody Therapy Discharge Instructions](#)

2. Patients treated with monoclonal antibody therapy should continue to use infection precautions and isolate or quarantine according to CDC Criteria for [Quarantine and Isolation](#)

3. Administrators of monoclonal antibody therapy should report all medication errors and serious adverse events within seven (7) days from the onset of the event. This can be found here: [http://www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm). Please note, all fields should be completed with as much detailed information as possible

**Oral Antivirals**

1. No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir authorized under this [EUA](#)

2. Refer to the [EUA Fact Sheet for PAXLOVID](#) to identify potential drug interactions to prevent elevated plasma concentrations

3. Treatment of overdosage for molnupiravir and PAXLOVID should consist of general supportive measures, including monitoring of vital signs and observations of the clinical status of the patient
Reporting & Billing
The graphic below illustrates provider cadence for sotrovimab and bebtelovimab allocation requests and reporting to NC DHHS and HHS. Note: providers are required to report sotrovimab weekly on Wednesdays and bebtelovimab daily.

**Weekly Cycle**

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit allocation request by Monday at 12pm</td>
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<tr>
<td></td>
<td></td>
<td>NC DHHS order confirmation &amp; order entry</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Receive mAbs shipment 2-3 days after order placed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Report sotrovimab administration and inventory data to NC DHHS by the following Wednesday at 12pm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report sotrovimab utilization to HHS by the following Wednesday at 11:59pm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report bebtelovimab administration and inventory data to HPOP daily (when open for business) by 11:59pm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The graphic below illustrates provider cadence for oral antivirals allocation requests and reporting to NC DHHS and HHS.

- **Monday**: Submit allocation request by every Monday at 12pm.
- **Tuesday**: NC DHHS order confirmation & order entry.
- **Wednesday**: Receive oral antivirals shipment 2-3 days after order placed.
- **Thursday**: Report administration and inventory data to HPOP daily (when open for business) by 11:59pm.

**PROVIDER ORAL ANTIVIRALS ALLOCATION REPORTING CADENCE**
PROVIDER EVUSHELD ALLOCATION REPORTING CADENCE

The graphic below illustrates new provider cadence for EVUSHELD allocation requests and reporting to NC DHHS and HHS.

Submit EVUSHELD allocation requests* any time

NC DHHS order processing Monday at 12pm

NC DHHS order confirmation & order entry

Shipments are received on a rolling basis and typically arrive 2-3 days after order is placed

Report administration and inventory data to HPOP daily by 11:59pm

*Request orders in cartons
REPORTING REQUIREMENTS

Providers should report Evusheld, molnupiravir, Paxlovid, and bebtelovimab in HPOP and continue reporting sotrovimab to NC DHHS and HHS Tele-tracking. Please reference [this document](#) for the correct way to report administrations and inventory in HPOP. See below for additional guidance:

**Weekly Cadence HHS Reporting:**

Although the NC DHHS oversees distribution and management of mAbs treatments to provider locations within the state, **ALL administering locations must continue to report via HHS tele-tracking** (reporting mechanisms may vary for hospitals). Information updates will continue to be uploaded on the HHS tele-tracking site.

**Weekly reminders and instructions** will also continue to be emailed to existing providers from TeleTracking’s Technical Support at [hhs-protect@teletracking.com](mailto:hhs-protect@teletracking.com).

**First-time users** will receive enrollment and reporting instructions in an e-mail from [protect-noreply@hhs.gov](mailto:protect-noreply@hhs.gov) with the subject line of “Invitation: HHS TeleTracking COVID-19 Portal.” This email provides step-by-step instructions to access the Portal for the first time.

Utilization reporting due **Wednesdays at 11:59am**

**Daily HPOP Reporting:**

Although the NC DHHS oversees distribution and management of EVUSHELD, Oral Antivirals (Molnupiravir and PAXLOVID), and bebtelovimab to provider locations within the state, **ALL administering locations must report administration and inventory data in HPOP DAILY for all days the location is open**. Reporting is not required when the facility is closed and not available for administering or dispensing. EVUSHELD should be reported in cartons, all other therapeutics should be reported in courses.

**Weekly Cadence Administration and Inventory Reporting:**

Although the NC DHHS oversees distribution and management of mAbs treatments to provider locations within the state, **ALL administering locations must continue to report administration and inventory data via this form** (reporting mechanisms may vary for hospitals).

**Weekly reminders and instructions** will also continue to be emailed to existing providers from the Therapeutics Inbox.

Admin and Inventory reporting due **Wednesdays at 12pm**
ADVERSE EVENT REPORTING

The prescribing healthcare provider and/or the provider’s designee are/is responsible for mandatory reporting of all serious adverse events and medication errors potentially related to the respective drug product within seven (7) days from the healthcare provider’s awareness of the event, using FDA Form 3500 (for information on how to access this form, see below).

Submit adverse event and medication error reports, using Form 3500, to FDA MedWatch using one of the following methods:
• Complete and submit the report online by visiting www.fda.gov/medwatch/report.htm
• Complete and submit a postage-paid FDA Form 3500 and return by:
  • Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20851-9787, or
  • Fax to 1-800-FDA-0178
• Call 1-800-FDA-1088 to request a reporting form

Please provide a copy of all FDA MedWatch forms to:

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>E-mail/Website</th>
<th>Fax Number</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>REGEN-COV</td>
<td>Regeneron Pharmaceuticals</td>
<td><a href="mailto:medical.information@regeneron.com">medical.information@regeneron.com</a></td>
<td>1-888-876-2736</td>
<td>1-844-734-6643</td>
</tr>
<tr>
<td>Bam/Ete</td>
<td>Eli Lilly and Company</td>
<td><a href="mailto:mailindata_gsmindy@lilly.com">mailindata_gsmindy@lilly.com</a></td>
<td>1-317-277-0853</td>
<td>1-855-545-5921</td>
</tr>
<tr>
<td>Sotrovimab</td>
<td>GlaxoSmithKline</td>
<td><a href="mailto:WW.GSKAEReportingUS@gsk.com">WW.GSKAEReportingUS@gsk.com</a></td>
<td>1-919-287-2902</td>
<td>1-866-475-2684</td>
</tr>
<tr>
<td>EVUSHELD</td>
<td>AstraZeneca</td>
<td><a href="https://contactazmedical.astrazeneca.com">https://contactazmedical.astrazeneca.com</a></td>
<td>1-866-742-7984</td>
<td>1-800-236-9933</td>
</tr>
<tr>
<td>PAXLOVID</td>
<td>Pfizer</td>
<td><a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a></td>
<td>1-866-635-8337</td>
<td>1-800-438-1985</td>
</tr>
<tr>
<td>Molnupiravir</td>
<td>Merck Sharp &amp; Dohme Corp.</td>
<td><a href="mailto:dpoc.usa@msd.com">dpoc.usa@msd.com</a></td>
<td>1-215-616-5677</td>
<td></td>
</tr>
<tr>
<td>VEKLURY</td>
<td>Gilead Sciences, Inc.</td>
<td><a href="mailto:safety_fc@gilead.com">safety_fc@gilead.com</a></td>
<td>1-650-522-5477</td>
<td>1-800-445-3235</td>
</tr>
<tr>
<td>Bebtelovimab</td>
<td>Eli Lilly and Company</td>
<td><a href="mailto:mailindata_gsmindy@lilly.com">mailindata_gsmindy@lilly.com</a></td>
<td>1-317-277-0853</td>
<td>1-855-545-5921</td>
</tr>
</tbody>
</table>
BILLING & REIMBURSEMENT

Please reference the following link for more detailed billing information:

- COVID-19 Monoclonal Antibody: Coding and Billing Guide
- Centers for Medicare & Medicaid Services (CMS) Guidance on Oral Antiviral Billing
- National Community Pharmacists Association COVID-19 Antivirals Dispensing and Reimbursement

CMS Code for Outpatient use of VEKLURY (remdesivir)

- Following the recent statement from National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel regarding therapies for COVID-19 Omicron variant, CMS created **HCPCS code J0248** for the VEKLURY (remdesivir) antiviral medication when administered in outpatient setting
- Code available for use by all payers
- Effective dates of service on or after December 23, 2021:
  - Long descriptor: Injection, remdesivir, 1 mg
  - Short descriptor: Inj, remdesivir, 1 mg
- Medicare Administrative Contractors (MACs) determine Medicare coverage when no national coverage determination, including when providers use FDA-approved drugs for indications other than what is on approved label
- MACs will determine Medicare coverage for HCPCS code J0248 for VEKLURY (remdesivir) administered in outpatient setting
- See **CMS COVID-19 Provider Toolkit** for additional information

Please reference the following link for more detailed billing information:

- COVID-19 Monoclonal Antibody: Coding and Billing Guide
- Centers for Medicare & Medicaid Services (CMS) Guidance on Oral Antiviral Billing
- National Community Pharmacists Association COVID-19 Antivirals Dispensing and Reimbursement

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- MACs will determine Medicare coverage for HCPCS code J0248 for VEKLURY (remdesivir) administered in outpatient setting
- See **CMS COVID-19 Provider Toolkit** for additional information
Comms
Providers can subscribe to the **NC DHHS Therapeutics Communication** to learn more about weekly updates and news. Weekly updates are sent out on Wednesdays. Confirmation of allocation request receipt is sent out on Fridays.

To get added to the distribution list, complete the **NC DHHS Therapeutics Provider Communications form**:

- If you would like to **add more than one email** to the distribution list, refresh page after submission and resubmit

- **Please note**, that there will be a separate link shared for new providers to register for a mAbs or oral antivirals account. Completing this form will only get you added to the NC DHHS therapeutics communications distribution list
Please send all questions to:
Therapeutics.COVID19@dhhs.nc.gov