Provider Playbook: COVID-19 Outpatient Therapeutics

October 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.
TABLE OF CONTENTS (1 OF 2)

All Treatment Options
- Product Specifications (1 of 2)
- Product Specifications (2 of 2)

mAbs Treatment
- Monoclonal Antibodies – Overview

Antiviral Treatment
- Oral Antivirals – Overview
- VEKLURY (remdesivir) – Overview

Treatment Prioritization
- Prioritization of COVID-19 Therapeutics
- All Treatment Products Prioritization
- Health Alert Network Health Advisory and NC Provider Memo
- COVID-19 Outpatient Therapeutics Decision Guide
- COVID-19 Outpatient Therapeutics Decision Guide – Pediatric Patients

Registration
- New Provider Registration
- Test to Treat (T2T) Overview
- Oral Antiviral Dispensing Guidance

Allocation & Site Finder
- How to Locate COVID-19 Therapeutics
- Site Finder Registration
- Updated Therapeutics Allocation Restrictions
- Requesting mAbs Replacement (1 of 4)
- Requesting mAbs Replacement (2 of 4)
- Requesting mAbs Replacement (3 of 4)
- Requesting mAbs Replacement (4 of 4)
- Requesting EVUSHELD Allocations (1 of 3)
- Requesting EVUSHELD Allocations (2 of 3)
- Requesting EVUSHELD Allocations (3 of 3)
- Requesting Oral Antivirals Allocations (1 of 3)
- Requesting Oral Antivirals Allocations (2 of 3)
- Requesting Oral Antivirals Allocations (3 of 3)

Monoclonal Antibodies
Antivirals

Please refer to this key throughout to find relevant information:
TABLE OF CONTENTS (2 OF 2)

Shipping & Storage
• Shipping & Storage

Preparation & Administration
• mAbs Preparation & Administration
• Oral Antivirals Preparation & Administration
• Vaccination Considerations
• PAXLOVID Packaging and Dosage Information

Post-Treatment Monitoring
• Post-treatment Patient Monitoring
• CDC Health Advisory: COVID-19 Rebound After PAXLOVID Treatment

Reporting & Billing
• Provider Therapeutics Allocation Reporting Cadence
• Provider EVUSHELD Allocation Reporting Cadence
• Reporting Requirements

Reporting & Billing (cont.)
• Adverse Event Reporting
• Billing & Reimbursement

Comms
• Therapeutics Communication

Additional Resources
• Includes: Therapeutics FAQs, NC Provider Office Hours, Therapeutics Inbox, Deauthorized Products and Shelf-Life Extensions

Deauthorized Products
• Product Specifications – Deauthorized
• Deauthorized mAbs Overview
• REGEN-COV Packaging and Labeling Information
All COVID-19 Treatment Options
**PRODUCT SPECIFICATIONS (1 OF 2)**

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### Bebtelovimab

- Manufactured by: Eli Lilly and Company
- Authorized dosage for bebtelovimab for treatment is 175 mg of bebtelovimab
- Bebtelovimab is authorized 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 authorized 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 (FDA does not consider VEKLURY to be an adequate alternative to bebtelovimab for this authorized use because it may not be feasible or practical for certain patients)
- 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 authorized 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 received only the previously authorized initial dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive an additional dose as soon as possible, with the dose based on the following criteria: 1) If the patient received their initial dose ≤ 3 months ago, the patient should receive a dose of 150 mg of tixagevimab and 150 mg of cilgavimab, and 2) If the patient received their initial dose > 3 months ago, the patient should receive a dose of 300 mg of tixagevimab and 300 mg of cilgavimab
- Providers should clinically monitor patients for at least one hour following the injection for reactions
- Updated EUA recommends repeat dose of 300 mg of tixagevimab and 300 mg of cilgavimab every six months
- Visit the [Health Care Provider Fact Sheet](#) for further provider guidance and information
**PRODUCT SPECIFICATIONS (2 OF 2)**

**PAXLOVID**
- Manufactured by: Pfizer
- Authorized standard dosage for PAXLOVID is a combination of 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), taken together orally twice daily for 5 days, with or without food
- Authorized renal impairment dosage for patients with moderate renal impairment (eGFR ≥30 to <60 mL/min) is 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), taken together orally twice daily for 5 days, with or without food
- PAXLOVID is authorized for adults and pediatric patients (age 12 and older)
- PAXLOVID can only be delivered as an oral pill
- PAXLOVID is authorized for treatment in patients with a positive COVID-19 test who are at high risk for progression to severe COVID-19
- Providers should monitor patients with potential drug interactions (list available [here](#)) for adverse reactions
- Visit the [Health Care Provider Fact Sheet](#) for further provider guidance and information

**LAGEVRIO (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 authorized for adults
- Molnupiravir can only be delivered as an oral pill
- Molnupiravir is authorized 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.
- Approved 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 (28 days of age and older and weighing at least 3 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 [Package Insert](#) for further provider guidance and information
mAbs Treatment
# MONOCLONAL ANTIBODIES – OVERVIEW

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. The following mAb products are currently authorized and 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>*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 12 years and older 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 all currently circulating variants</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 12 years and older who are immunocompromised or have a contraindication for COVID-19 vaccines</td>
<td>No – per FDA/HHS</td>
<td>77% effective in preventing SARS-CoV-2 RT-PCR symptomatic illness. Higher dose may be more likely to prevent infection by the COVID-19 circulating variants. **Repeat dosing every 6 months</td>
</tr>
</tbody>
</table>

*Bebtelovimab is now available commercially from AmeriSource Bergen.

*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. The following oral antivirals products are currently authorized and are effective against currently circulating SARS-CoV-2 variants. 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, LAGEVRIO</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 <strong>within five (5) days of symptom onset</strong> Not recommended during pregnancy</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>Nirmatrelvir / Ritonavir</td>
<td>PAXLOVID, 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 <strong>within five (5) days of symptom onset</strong> Dosage adjustment required for moderate renal impairment (eGFR ≥30 to &lt;60 mL/min) Extensive drug interactions list</td>
<td><strong>Standard:</strong> 300 mg of nirmatrelvir and 100 mg of ritonavir twice-daily for five (5) days <strong>Renal impairment:</strong> 150 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>
</tbody>
</table>
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 in both hospitalized and non-hospitalized patients who are at least 28 days of age and older and weighing at least 3 kg.


<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Also known as</th>
<th>Approved Indication</th>
<th>Route of Administration</th>
<th>Administration Requirements</th>
<th>Dosing Regimen</th>
<th>Approved Patient Population</th>
<th>Standing Order?</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remdesivir</td>
<td>VEKLURY</td>
<td>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</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. For non-hospitalized patients, treatment must be initiated as soon as possible after diagnosis and within seven (7) days of symptom onset.</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. 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>Adults and pediatric patients <a href="https://www.gilead.com/">28 days of age and older and weighing at least 3 kg</a>.</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. Retains efficacy against Omicron.</td>
</tr>
</tbody>
</table>
Treatment Prioritization
Currently, COVID-19 therapies, especially oral antivirals, are widely available across the state. Anyone with a COVID-19 diagnosis who is considered high risk should be carefully evaluated for potential treatment options, and treatment should not be withheld if the patient qualifies under the EUA.

During surges in cases of SARS-CoV-2 infection, logistical or supply constraints may make it impossible to offer available therapeutics to all the non-hospitalized patients who are eligible to receive them. In these situations, it may be necessary to prioritize therapy based on age, vaccination status, immune status, or presence of risk factors.

NC DHHS is continuously monitoring supply of all COVID-19 therapeutics and will update these recommendations on patient prioritization, as necessary.
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. 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. Lagevrio (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. Sotrovimab is no longer authorized for use due to available data that shows it is not effective against the BA.2 Omicron sub-variant.

*Remdesivir is not allocated by the federal government and is only available for private purchase
A large proportion of the North Carolina population is considered high risk based on age or underlying conditions. Therefore, anyone with a COVID-19 diagnosis should be carefully evaluated for potential treatment options. These therapies have demonstrated effectiveness against currently circulating SARS-CoV-2 variants, and many have been clinically proven to be effective in preventing hospitalization or death.

Please refer to this memo for provider guidance for outpatient treatment and prevention of coronavirus disease 2019 (COVID-19) in patients who are at high risk of progressing to severe disease.

Health Alert Network (HAN) Health Advisory (linked):
The Centers for Disease Control and Prevention (CDC) has issued this Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public about the availability and use of recommended therapies for COVID-19 and to advise against using unproven treatments that have known or potential harms for outpatients with mild to moderate COVID-19. For patients with mild to moderate COVID-19 who are not hospitalized and who are at increased risk for severe COVID-19 outcomes, several treatment options, including antiviral medications and monoclonal antibodies, are now widely available and accessible.
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
- Requiring O₂
- Requiring an increase in baseline home O₂ due to COVID-19?

Consider one of the following therapeutics, if available, feasible, and clinically appropriate:\n
Paxlovid\(^2\) within 5 days of symptom onset If patient does not have severe renal impairment (eGFR <30 mL/min OR severe hepatic impairment (Child-Pugh Class C)
- eGFR ≥ 80 mL/min: 300 mg nirmatrelvir taken with 100 mg ritonavir twice daily for 5 days
- eGFR ≥ 30 to < 60: 150 mg nirmatrelvir taken together with 100 mg ritonavir twice daily for 5 days
- Evaluate concomitant use of CYP3A inducers and medications with high dependency on CYP3A for clearance as these may be contraindicated\(^2,3\)

OR

Veklury (remdesivir)\(^2\) 200 mg IV x 1 dose on Day 1, 100 mg IV x 1 on Days 2–3 begun ASAP within 7 days of symptom onset

If Paxlovid and Veklury (remdesivir) are not available, feasible or clinically appropriate consider one of the following therapeutics:

bebtelovimab\(^6\) ASAP within 7 days of symptom onset

175 mg single IV injection

OR

Lagevrio (molnupiravir)\(^6\) if patient age 18 or older AND possibility of pregnancy, if applicable, ruled out:

800 mg by mouth every 12h for 5 days begun ASAP within 5 days of symptom onset

Prescribers must review and comply with the mandatory requirements outlined in the Lagevrio (molnupiravir) EUA\(^6\)

\(^2\) PAXLOVID EUA. https://www.fda.gov/media/13552/download\n
\(^5\) Bebtelovimab EUA. https://www.fda.gov/media/155054/download\n
\(^6\) Lagevrio (molnupiravir) EUA. https://www.fda.gov/media/155050/download
COVID-19 Outpatient Therapeutics
Clinical Decision Aid for Pediatric Patients
Outpatient 28 days of age and older weighing at least 3 kg to less than 40 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)
- NO: Treatment of symptoms, management per NIH & CDC Guidelines

Consider Veklury (remdesivir)\(^\ast\) 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 28 days of age and older weighing at least 3 kg to less than 40 kg: 5 mg/kg IV on Day 1, 2.5 mg/kg on Days 2–3

\(^\ast\)Use 100 mg lyophilized vial for EUA pediatric use

\(^\ast\) Veklury Prescribing Information: https://www.gilead.com/-/media/files/medicines/covid-19/veklury/veklury_pi.pdf
Special Considerations in People Who are Immunocompromised

The COVID-19 Treatment Guidelines Panel (the Panel) recommends COVID-19 vaccination for all people who are moderately or severely immunocompromised (AIII).

The Panel recommends using tixagevimab plus cilgavimab (Evusheld) as SARS-CoV-2 pre-exposure prophylaxis (PrEP) for adults and adolescents who do not have SARS-CoV-2 infection or recent exposure to an individual with SARS-CoV-2 infection and who are moderately to severely immunocompromised and may have an inadequate immune response to COVID-19 vaccination (BIIb).

There is insufficient evidence for the Panel to recommend either for or against the use of SARS-CoV-2 serologic testing to assess for immunity or to guide clinical decisions about using COVID-19 vaccines or anti-SARS-CoV-2 monoclonal antibodies (mAbs) as PrEP in certain people.
In addition to following the recommended COVID-19 vaccination schedule, **tixagevimab plus cilgavimab (Evusheld)**, should be administered to people who are moderately or severely immunocompromised every 6 months for pre-exposure prophylaxis to supplement vaccine protection. Per the product EUA, Evusheld is given at least 2 weeks after COVID-19 vaccine. People may initiate Evusheld at any time after this interval, including between doses in the primary series and primary and booster doses.

Providers should consult CDC’s Evusheld guidance and current treatment guidelines for more information on the use of Evusheld as pre-exposure prophylaxis. Such use of monoclonal antibodies, however, is not a substitute for COVID-19 vaccination.

**Advisory Committee on Immunization Practices (ACIP) Recommends EVUSHIELD**
Registration
NEW PROVIDER REGISTRATION

To register your organization or clinical site to receive allocations of the federally purchased supply of COVID-19 therapeutic products (Paxlovid, Lagevrio, and EVUSHELD), please complete the [NC DHHS COVID-19 Therapeutics Site Registration 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 to 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 – FAQ](#).

*Ordering therapeutics and provider registration has transitioned from the C19 ABC Portal to HPOP as of 14 FEB 22.*
Test to Treat (T2T) is a nationwide initiative that provides individuals a more effective way to rapidly access lifesaving treatment for COVID-19

In this program, people can get tested and – if they are positive and treatments are appropriate for them – receive a prescription from a healthcare provider, and have their prescription filled all in one location.

If interested in becoming a Test to Treat provider, please fill out the NC DHHS COVID-19 Therapeutics Site Registration Form. Please see requirements below:

• Rapid COVID-19 testing on-site (or evaluation of at-home testing)
• Linkage to a clinical evaluation by licensed healthcare provider after positive result to provide prescription when appropriate
• Co-located pharmacy* able to readily dispense medication to eligible patients
• Provide services to all individuals, regardless of insurance status

Click here to view the COVID-19 Test to Treat Fact Sheet

Providers who meet these criteria have the option to be identified as a Test to Treat location on both the NC DHHS and the federal COVID-19 Therapeutics Site Finder Tool

Note: The Treatment Finder, found here, is available and accessible for the general public seeking COVID-19 treatment

*See next slide for NC specific dispensing guidance
ORAL ANTIVIRAL DISPENSING GUIDANCE

Physicians, pharmacists, 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.
ORAL ANTIVIRAL DISPENSING GUIDANCE

The revised Paxlovid (nirmatrelvir and ritonavir) Emergency Use Authorization (EUA) authorized state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations. Paxlovid may be prescribed for an individual patient by a state-licensed pharmacist under the following conditions:

1. Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and
2. Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

The state-licensed pharmacist should refer an individual patient for clinical evaluation (e.g., telehealth, in-person visit) with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

1. Sufficient information is not available to assess renal and hepatic function.
2. Sufficient information is not available to assess for a potential drug interaction.
3. Modification of other medications is needed due to a potential drug interaction.
4. Paxlovid is not an appropriate therapeutic option based on the authorized Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

The July 6th FDA announcement can be found here and the revised Paxlovid EUA can be accessed here.
Allocation & Site Finder
HOW TO LOCATE COVID-19 THERAPEUTICS

The ‘Find Treatment’ section on the NC DHHS website includes an updated ‘Treatments Finder’ tool that enables recipients to: 1) Search for nearby Testing and Test to Treat sites, 2) Discover available treatments each site offers for administration and/or prescriptions, 3) Find resources to schedule an appointment (phone numbers, websites)
SITE FINDER PROVIDER INFORMATION SURVEY

All providers serving the greater population (excluding long-term care facilities, hub locations, and non-public facing providers) 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 that are open to the public and reporting positive therapeutics inventory will be automatically added to the Site Finder.**

To update information to your posting on the Site Finder tool, please complete the **Site Finder Provider Information survey.**

Your location will be listed on the **Find Treatment** locator 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 via the COVID-19 Testing and Treatments Inquiry Intake Form.
- 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 on 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 the treatments team via the COVID-19 Testing and Treatments Inquiry Intake Form 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 continues to manage United States Government (USG) purchased bebtelovimab. Effective August 29th, all USG supplied product has been stockpiled for patients who are uninsured/underinsured.

Providers may request replacement vials from the NC DHHS bebtelovimab stockpile when a commercially purchased vial is used to treat patients who are uninsured or underinsured.

**To request replacement product:** Complete the NC DHHS Bebtelovimab Replacement Request Form

- Providers must be registered in HPOP and submit requests every **Monday by 12pm EST**, to receive the number of vials commensurate with the number of patients treated who were uninsured or underinsured
- Providers may anticipate an overnight delivery within the same week of the request

Final allocations can be found on the Allocations Summary Page of the Provider Hub.

For guidance on ordering the commercially available bebtelovimab, please contact c19therapies@amerisourcebergen.com
NC DHHS Bebtelovimab Replacement Request Form

EVERY WEEK

SUBMIT BEBTEOLOVIMAB REQUEST

Requests must be received by Monday at 12PM to be considered for shipment that week

MONDAY 12:00PM

REQUEST REVIEW

NC DHHS will review all requests to ensure requests are in line with guidelines below

TUESDAY

REQUEST APPROVED

NC DHHS ORDER CONFIRMATION

ORDER SHIPPED

SHIPMENT TYPICALLY ARRIVES 2 DAYS AFTER THE REQUEST

In most cases, denied requests will be due to failure to meet ordering guidelines, reporting discrepancy in HPOP, or insufficient inventory to fill the request. Please only request the number of vials equal to the number of patients you have treated that were uninsured/underinsured in the prior week (Sunday to Saturday).

If you believe your bebtelovimab request was denied in error, please review the ordering guidelines and resubmit to be considered in the next allocation.
NC DHHS reviews all requests to ensure orders align with state request guidelines and reporting in HPOP.

State request guidelines for bebtelovimab is provided below:

<table>
<thead>
<tr>
<th>Bebtelovimab (Eli Lilly)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minimum Replacement Quantity</strong></td>
</tr>
<tr>
<td><strong>Maximum Replacement Request</strong></td>
</tr>
<tr>
<td><strong>Reporting Method</strong></td>
</tr>
<tr>
<td><strong>Direct Ship Available</strong></td>
</tr>
</tbody>
</table>
Patient is eligible for Bebtelovimab

**Insured**
Medicaid/Medicare/Private

**Uninsured**
Or
**Underinsured**

**Commercially Purchased Product***
(direct from AmerisourceBergen)

**Use USG supply current on hand first**

**Commercially Purchased Product**
(at no cost to the patient)

*If your facility cannot manage two separate billing mechanisms for commercially purchased vs. USG-supplied inventory, then it is acceptable to use your USG-supplied product for all patients first, before purchasing commercial product.

Request free replacement doses from NC DHHS
REQUESTING EVUSHELD ALLOCATION (1 OF 4)

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.

NC DHHS will send order confirmations of allocation request receipts via the Therapeutics Mailbox every Monday. Final allocations can be found on the Allocations Summary Page of the Provider Hub.
To request and receive shipment, providers must be registered within Health Partners Ordering Portal (HPOP). For the current registration process, please refer to slide 22.
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><strong>Minimum Order Quantity (MOQ)</strong></th>
<th><strong>EVUSHELD (AstraZeneca)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12 <em>(NOTE: this number represents 6 patient courses)</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Maximum Order Request</strong></th>
<th><strong>If requesting &gt; MOQ: Only order enough inventory to meet one (1) week of utilization demand</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Reporting Method</strong></th>
<th><strong>All administrations must be reported twice per week by 11:59 pm on Monday and Thursday in cartons via the HPOP when location is open</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Ship Available</td>
<td>Yes</td>
</tr>
</tbody>
</table>
REQUESTING EVUSHELD ALLOCATIONS (4 OF 4)

Please note that there is a new call line for Evusheld product and ordering information

1-833-EVUSHLD (833-388-7453)

There is also an additional pathway established for small volume ordering. Please visit OrderEvusheld.com for individual providers seeking small quantities of product (1-3 patient courses).
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

NC DHHS will send order confirmations of allocation request receipts via the Therapeutics Mailbox every Monday. Final allocations can be found on the Allocations Summary Page of the Provider Hub.

"Renal" PAXLOVID Note: As of April 14th, 2022, Pfizer offers a "renal" PAXLOVID packaging. This packaging contains the 150mg nirmatrelvir with 100 mg ritonavir dosing required for renally impaired patients and replaces the sticker method providers have previously used to manually adjust regular PAXLOVID packaging. "Renal" PAXLOVID can be requested using the existing PAXLOVID request survey.
REQUESTING ORAL ANTIVIRALS ALLOCATIONS (2 OF 3)

Click [here](#) to request PAXLOVID and [here](#) to request molnupiravir.

**EVERY WEEK**

**SUBMIT ORAL ANTIVIRAL REQUEST**
Requests must be received by **Monday at 12pm**, of allocation week to be considered for shipment.

**MONDAY-TUESDAY**

**REQUEST REVIEW**
NC DHHS will review all requests to ensure requests are in line with guidelines below.

In most cases, denied requests will be due to insufficient allocation, inadequate provider level utilization reporting, more than 3 weeks of on-hand inventory and/or insufficient local demand. Please only request what you can fully exhaust within one (1) week of receipt.

If you believe your oral antiviral request was denied in error, please review the ordering guidelines below and resubmit to be considered in the next allocation.

**TUESDAY-WEDNESDAY**

**NC DHHS ORDER CONFIRMATION & ORDER ENTRY**

**ORDERS DELIVERED**

**SHIPMENT TYPICALLY ARRIVES 2-3 DAYS AFTER ORDERS PLACED**

To request and receive shipment, providers must be registered within the Health Partners Ordering Portal (HPOP). For the current registration process, please refer to [slide 22](#).
**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 – Standard Dosage (Pfizer)</th>
<th>PAXLOVID – Renal Dosage (Pfizer)</th>
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</thead>
<tbody>
<tr>
<td>15</td>
<td>20</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

**Maximum Order Request**

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

**Reporting Method**

All administrations must be reported **twice per week** by 11:59pm on Monday and Thursday via the HPOP 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 customersystems@mAb@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)

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Visit [ABC’s Tracking Tool Website](#) to track order status.
- Use account # provided by ABC
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- **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 (Standard Dosage)**: 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
   - **PAXLOVID (Renal Dosage)**: The dosage for PAXLOVID is 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) with all two tablets taken together orally twice daily for five (5) days, with or without food
     - Dosage required for patients with moderate renal impairment (eGFR ≥30 to <60 mL/min). No dosage adjustment is needed in patients with mild renal impairment (eGFR ≥60 to <90 mL/min). PAXLOVID is not recommended in patients with severe renal impairment (eGFR <30 mL/min). Please refer to the HCP Letter for further information
     - 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

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](https://www.cdc.gov).
PAXLOVID PACKAGING & DOSAGE INFORMATION

Please be aware that PAXLOVID has multiple packaging types, and it is essential you take note of the differences when requesting and prescribing the product.

Packaging: The PAXLOVID™ may arrive in one of two (2) packaging configurations:

For patients without, or with mild, renal impairment (eGFR ≥60 mL/min):
PAXLOVID™ with 30 tablets - 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet)

For patients with moderate renal impairment (eGFR ≥30 or <60 mL/min):
PAXLOVID™ with 20 tablets - 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet)

It is important that providers and those requesting and/or prescribing the product pay close attention to the dosage and refer to the QR code enclosed with the product for updates. Please refer to the HCP Letter for the latest information and instructions for each dosage.
Post-Treatment Monitoring
POST-TREATMENT PATIENT MONITORING

mAbs

1. Providers should clinically monitor patients for at least one hour after infusion is complete for reactions
2. Provide to and review with the patient: COVID-19 Antibody Therapy Discharge Instructions
3. Patients treated with monoclonal antibody therapy should continue to use infection precautions and isolate or quarantine according to CDC Criteria for Quarantine and Isolation
4. 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. 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 Pfizer’s Potentially Significant Drug Interactions, the EUA Fact Sheet for PAXLOVID to identify potential drug interactions with PAXLOVID, or the Pharmacists Prescriptive Authority Guidance
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
The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public on the potential for recurrence of COVID-19 or “COVID-19 rebound.”

- The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public on the potential for recurrence of COVID-19 or “COVID-19 rebound.”
- **PAXLOVID continues to be recommended for early-stage treatment of mild to moderate COVID-19 among persons at high risk for progression to severe disease.**
- PAXLOVID treatment helps prevent hospitalization and death due to COVID-19. COVID-19 rebound has been reported to occur between 2 and 8 days after initial recovery and is characterized by a recurrence of COVID-19 symptoms or a new positive viral test after having tested negative.
- **A brief return of symptoms may be part of the natural history of SARS-CoV-2 (the virus that causes COVID-19) infection in some persons, independent of treatment with Paxlovid and regardless of vaccination status.**
- Limited information currently available from case reports suggests that persons treated with PAXLOVID who experience COVID-19 rebound have had mild illness; there are no reports of severe disease.
- Find more information regarding the CDC Health Advisory [here](#).
Reporting & Billing
The graphic below illustrates provider cadence for oral antivirals and bebtelovimab 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

**Friday**
- Receive therapeutics shipment 2-3 days after order placed

**Saturday**
- Report administration and inventory data to HPOP by 11:59pm

**Sunday**
- Report administration and inventory data to HPOP by 11:59pm
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 by 11:59pm

*Request orders in cartons
REPORTING REQUIREMENTS

Providers should report currently authorized therapeutics (EVUSHELD, molnupiravir, PAXLOVID, and USG-supplied bebtelovimab) in HPOP, and report previously authorized therapeutics (sotrovimab, REGEN-COV, and Bam/Ete) to NC DHHS and HHS Tele-tracking. See below for additional guidance:

**For Currently Authorized COVID-19 Therapeutics:**

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 twice per week by 11:59pm on Monday and Thursday for all days the location is open.** Reporting is not required when the facility is closed and not available for administering or dispensing. Reporting must include what you have administered since you last reported and is **NOT** cumulative. EVUSHELD should be reported in cartons, all other therapeutics should be reported in courses.

**NOTE:** Bebtelovimab purchased commercially should **NOT** be reported in HPOP.

Please reference [this document](#) for the correct way to report administrations and inventory in HPOP.

**For Previously Authorized COVID-19 Therapeutics:**

The Federal government continues to encourage providers to hold on to previously authorized therapeutics, including sotrovimab, REGEN-COV, and bamlanivimab/etesevimab. Providers should continue to report weekly inventory levels of these products via the following mechanisms:

1. **Federal HHS Utilization Report via HHS Tele-Tracking due Wednesdays at 11:59pm (not applicable for hospitals) until November 2nd, 2022, when reporting transitions to HPOP.**

2. **North Carolina Weekly COVID-19 Therapeutic Inventory Form due Wednesdays at 12:00pm (applicable to all providers)**

**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.
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_gsmtindy@lilly.com">mailindata_gsmtindy@lilly.com</a></td>
<td>1-317-277-0853</td>
<td>1-855-545-5921</td>
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<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>
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<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>
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<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>
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<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>
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<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>
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<td>Bebtelovimab</td>
<td>Eli Lilly and Company</td>
<td><a href="mailto:mailindata_gsmtindy@lilly.com">mailindata_gsmtindy@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
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
Additional Resources
ADDITIONAL RESOURCES

Therapeutics FAQs
Reference this site for FAQs regarding COVID-19 mAbs, oral antivirals, treatment, and other questions

NC Provider Office Hours
Attend monthly Teams meetings on the second Friday of the month at 12pm for questions regarding therapeutic products and the ordering and allocation process (meeting invite link provided in Therapeutics Newsletter)

Therapeutics Inquiries
Submit a question via the COVID-19 Testing and Treatments Inquiry Intake form.

Deauthorized Products
Please refer to this section for guidance on deauthorized products: REGEN-COV and Bam'Ete are not authorized for use at this time due to their markedly reduced activity against the Omicron variant, Sotrovimab is not authorized for use at this due to its markedly reduced activity against the BA.2 Omicron sub-variant.
Recently, FDA has announced shelf-life extension guidelines for multiple therapeutics products:

**Evusheld:**
- FDA authorized extension to the shelf-life **from 18 months to 24 months** for **specific lots** of the refrigerated AstraZeneca monoclonal antibody therapy, Evusheld.
- **NOTE:** Lot #AZ220049 expires on August 31, 2022 and will not have an extended expiration date. FDA asks that sites use this product in the next few weeks.

**REGEN-COV:**
- On June 27, FDA authorized an extension to the shelf-life **from 24 months to 30 months** for **specific lots** of REGEN-COV.

Please refer to the [Therapeutics Provider Hub](#) for the most updated information with regards to shelf-life extension announcements.
ADDITIONAL RESOURCES

Shelf-Life Extensions

Paxlovid:

Lots of Paxlovid with dates of expiry from July 2022 to May 2023 may be stored for an additional six months from the labeled date of expiry when stored according to the storage conditions detailed in the authorized Fact Sheet for Health Care Providers.

FDA granted this extension following a thorough review of data submitted by Pfizer.

The full announcement is available on the ASPR website.

Please refer to the Therapeutics Provider Hub for the most updated information with regards to shelf-life extension announcements.
Paxlovid Clinical Resources

To assist with clinical decision making, please see resources below:

- Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers
- Liverpool COVID-19 Drug Interactions
- FDA Updates on Paxlovid for Health Care Providers
- Paxlovid – Pfizer Site
- American Pharmacist Association Test to Treat for Paxlovid
- ASPR Paxlovid Information Sheet

Please refer to the Therapeutics Provider Hub for more resources.
**ADDITIONAL RESOURCES**

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**Know Before You Go: What to tell patients**

**Know Your Status**

**Know Your Location**
- Your nearest Test-To-Treat location found at [Find A Test To Treat Location | NC COVID-19 (ncdhhs.gov)](https://ncdhhs.gov)

**Know Your Treatment Options**
- Find COVID19 treatment options at [Treatments (ncdhhs.gov)](https://ncdhhs.gov)

**Know Your Rights**
- Download and print a [Know Your Rights pocket card](https://ncdhhs.gov)
Deauthorized Products
PRODUCT SPECIFICATIONS - DEAUTHORIZED

**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 Baml/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**

Please note: treatment is not authorized for use at this time due to the markedly reduced activity against BA.2 Omicron sub-variant

- 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
DEAUTHORIZED MONOCLONAL ANTIBODIES – OVERVIEW

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, Sotrovimab is not authorized for use at this time due to its markedly reduced activity against the BA.2 Omicron sub-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. As previously mentioned, the following are not authorized for use for COVID-19 at this time:

<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>Post-exposure Prophylaxis, Treatment within 10 days of symptoms</td>
<td>Intravenous Infusion</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>
<td>COVID-19 Treatment within seven (7) days of symptoms</td>
<td>Intravenous Infusion</td>
<td>500 mg of sotrovimab</td>
<td>Patients aged 12 years and older and weighing at least 40 kg</td>
<td>No, rescinded April 6th</td>
<td>79% effective in preventing hospitalizations or death.</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>Limited effectiveness against the BA.2 Omicron sub-variant</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
REGEN-COV PACKAGING & LABELING INFORMATION

Please be aware that REGEN-COV has multiple packaging types. While REGEN-COV is no longer authorized for administration as COVID-19 treatment, providers should remain familiar with package types and labeling described below.

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 states the subcutaneous route is appropriate.
Questions?

Submit all inquiries and feedback via the COVID-19 Testing and Treatments Inquiry Intake Form.