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Summary of COVID-19 Preventative Agents & Therapeutics

**ORAL ANTIVIRALS**
- Paxlovid (Pfizer)
- Molnupiravir (Merck)

**MONOCLONAL ANTIBODIES FOR TREATMENT**
- Sotrovimab (GSK/Vir)
- Bamlanivimab + Etesevimab (Lilly)**
- Casirivimab + Imdevimab (RGN)**

**COVID-19 VACCINES**

**MOGOCLOAL ANTIBODIES FOR PEP**
- Tixagevimab + cilgavimab (AZ)
- Casirivimab + Imdevimab (RGN)**
- Bamlanivimab + Etesevimab (Lilly)**

**MOGOCLOAL ANTIBODIES FOR PREP**
- Tixagevimab + cilgavimab (AZ)
- Casirivimab + Imdevimab (RGN)**

**MONOCLONAL ANTIBODIES FOR PEP**
- Casirivimab + Imdevimab (RGN)**
- Bamlanivimab + Etesevimab (Lilly)**

**MONOCLONAL ANTIBODIES FOR TREATMENT**
- Sotrovimab (GSK/Vir)
- Bamlanivimab + Etesevimab (Lilly)**
- Casirivimab + Imdevimab (RGN)**

**ORAL ANTIVIRALS**
- Paxlovid (Pfizer)
- Molnupiravir (Merck)

**COVID-19 TREATMENT GUIDELINES PANEL’S STATEMENT ON SARS-COV2 MONOCLONAL ANTIBODIES OR REMDESIVIR FOR THE TREATMENT OF COVID-19 IN NONHOSPITALIZED PATIENTS WHEN OMICRON IS THE PREDOMINANT CIRCULATING VARIANT**

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

**Tools to Assist in COVID-19 Outpatient Therapeutic Selection**

As variant prevalence changes and new therapeutics become available, there are tools and resources available to assist in clinical decision-making for prescribers.

- Clinical Decision Aid: A pathway for decision-making including outpatient parenteral and oral therapeutics

- [Side-by-Side Overview of Outpatient Therapeutics](https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/Side-by-Side-Overview-of-mAbs-Treatment.aspx)


- [The COVID-19 Treatment Guidelines Panel’s Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints](https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/)

- [The COVID-19 Treatment Guidelines Panel's Statement on Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications](https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/)
Adult or pediatric (age 12 and older and weight 40kg or greater) with mild to moderate COVID-19 & high risk for progression to severe disease

Is Patient:
- Hospitalized for COVID-19 OR
- Requiring O₂ OR an increase in baseline home O₂ due to COVID-19

Yes

No

Symptom onset within the past 5-7 days?

Yes

No

Symptom onset within the past 10 days?

Yes

Consider the following (symptoms within 10 days):
- sotrovimab 500 mg IV within ASAP 10 days of symptom onset (sotrovimab EUA)

No

Does patient have severe renal impairment (eGFR <30mL/min) OR severely hepatic impairment (child-pugh class C)

Yes

No

Consider one of the following therapeutics, if available:
- Paxlovid within 5 days of symptom onset
  eGFR 60 mL/min or greater: 300mg nirmatrelvir taken with 100mg ritonavir twice daily for 5 days
  eGFR >30-<60: 150mg nirmatrelvir taken together with 100mg 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 per Paxlovid EUA
- sotrovimab 500 mg IV within ASAP 10 days of symptom onset (sotrovimab EUA)
- Remdesivir 200mg IV x 1 dose on day 1, 100mg IV x1 on days 2-3 begun ASAP and within 7 days of symptom onset ¹

If none of the above therapeutics are available for patient treatment within 5 days of symptom onset and patient is age 18 or greater

Possibility of pregnancy, if applicable, is ruled out?

Yes

Consider molnupiravir
- Authorized only in patients ages 18 and older
- Within 5 days of symptom onset
- Molnupiravir 800mg by mouth every 12h for 5 days
- Prescribers must review and comply with the mandatory requirements outlined in the molnupiravir EUA

No

Treatment of symptoms, Management per NIH & CDC Guidelines

Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant ²

¹Refer to the NIH COVID-19 Treatment Guidelines Panel’s Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

²COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)
mAb Susceptibility to CDC Variants of Concern

- Information on variants of concern updated in Section 15 of FDA fact sheets for monoclonal antibodies
- bamlanivimab/etesevimab and REGEN-COV are not expected to be active against the Omicron variant; sotrovimab is expected to retain activity against omicron
- The CDC monitors and publishes variant information on the CDC Covid Data Tracker https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Recommendations for Providers:

- If Delta still represents a significant proportion of infections locally and other options are not available, eligible patients offered bamlanivimab/ etesevimab or REGEN-COV must be informed these therapeutics are likely ineffective if infected with Omicron.

Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab (https://www.fda.gov/media/145802/download)
Fact Sheet for Health Care Providers Emergency Use Authorization for EVUSHELD (https://www.fda.gov/media/154701/download)
Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COVTM (casirivimab and imdevimab) (https://www.fda.gov/media/145611/download)
Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab (https://www.fda.gov/media/149534/download)

NIH COVID-19 monoclonal antibody guidelines when there are logistical constraints

- The NIH COVID-19 Treatment Guidelines Panel recommends using anti-SARS-CoV-2 monoclonal antibodies for the treatment of mild to moderate COVID-19 and for post-exposure prophylaxis (PEP) of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19, as outlined in the FDA Emergency Use Authorizations (EUAs). See the individual EUAs for details.

- Logistical constraints (e.g., limited space, not enough staff who can administer therapy) can make it difficult to administer these agents to all eligible patients. In situations where it is necessary to triage eligible patients, the Panel suggests:
  - Prioritizing the treatment of COVID-19 over PEP of SARS-CoV-2 infection.
  - Prioritizing the following groups over vaccinated individuals who are expected to have mounted an adequate immune response:
    - Unvaccinated or incompletely vaccinated individuals who are at high risk of progressing to severe COVID-19
    - Vaccinated individuals who are not expected to mount an adequate immune response (e.g., immunocompromised individuals).

- Providers should use their clinical judgment when prioritizing treatments in a specific situation. When there are no logistical constraints for administering therapy, these considerations should not limit the provision of anti-SARS-CoV-2 monoclonal antibodies.
2. Overview of Emergency Use Authorizations
The Role of Emergency Use Authorization (EUA) in COVID-19 Therapeutics

Q: What is an emergency use authorization and how is it being used to respond to COVID-19

A: In certain types of emergencies, the FDA can issue an emergency use authorization, or EUA, to provide more timely access to critical medical products (including medicines and tests) that may help during the emergency when there are no adequate, approved, and available alternative options.

The EUA process is different than FDA approval, clearance, or licensing because the EUA standard may permit authorization based on significantly less data than would be required for approval, clearance, or licensing by the FDA. This enables the FDA to authorize the emergency use of medical products that meet the criterial within weeks rather than months to years.

EUAs are in effect until the emergency declaration ends but can be revised or revoked as we evaluate the needs during the emergency and new data on the product’s safety and effectiveness, or as products meet the criteria to become approved, cleared, or licensed by the FDA.

About Emergency Use Authorizations (EUAs)
## Monoclonal Antibody Indications and Routes of Administration

<table>
<thead>
<tr>
<th>Monoclonal Antibody</th>
<th>PRE-EXPOSURE PROPHYLAXIS (PREP) for eligible individuals</th>
<th>POST-EXPOSURE PROPHYLAXIS (PEP) for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease</th>
<th>TREATMENT of Mild to Moderate COVID-19 Infection within 10 days of symptom onset in patient with high risk of progression to severe disease</th>
</tr>
</thead>
</table>
| bamlanivimab and etesevimab¹ (Eli Lilly) | N/A | Dose: bamlanivimab 700mg and etesevimab 1400mg  
Route: Intravenous  
Post-administration observation: 60 minutes  
*Weight-based pediatric (< 40kg) dosing*¹ | Dose: bamlanivimab 700mg and etesevimab 1400mg  
Route: Intravenous  
Post-administration observation: 60 minutes  
*Weight-based pediatric (< 40kg) dosing*¹ |
| casirivimab and imdevimab² (REGEN-COV) | N/A | Dose: casirivimab 600mg and imdevimab 600mg  
Route: Intravenous is preferred route, however subcutaneous injection may be utilized in situations where there would be a delay in intravenous administration  
Post-administration monitoring: 60 minutes | Dose: casirivimab 600mg and imdevimab 600mg  
Route: Intravenous or subcutaneous  
Post-administration monitoring: 60 minutes |
| sotrovimab³ (Glaxo Smith Kline) | N/A | N/A | Dose: sotrovimab 500mg  
Route: Intravenous  
Post-administration monitoring: 60 minutes |
| tixagevimab and cilgavimab⁴ (AstraZeneca) | Dose: tixagevimab 150mg and cilgavimab 150mg  
Route: Intramuscular  
Post-administration monitoring: 60 minutes | N/A | N/A |

**Not expected to retain activity against omicron variant**

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant


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¹ Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab (https://www.fda.gov/media/145802/download)

² Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COV™ (casirivimab and imdevimab) (https://www.fda.gov/media/145611/download)

³ Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab (https://www.fda.gov/media/149534/download)

⁴ Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab) (https://www.fda.gov/media/154701/download)
## Oral Antiviral Indications and Dosing

<table>
<thead>
<tr>
<th>Antiviral Agent</th>
<th>PRE-EXPOSURE PROPHYLAXIS (PREP) for eligible individuals</th>
<th>POST-EXPOSURE PROPHYLAXIS (PEP) for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease</th>
<th>TREATMENT of Mild to Moderate within 5 days of symptom onset in patients with high risk or progression to severe disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paxlovid (Pfizer)</td>
<td>N/A</td>
<td>N/A</td>
<td><strong>Dose:</strong> eGFR ≥60 ml/min: 300mg nirmatrelvir (#2 150mg tablets) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days eGFR ≥30 to &lt;60 mL: 150mg nirmatrelvir (#1 150mg tablet) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days Severe renal impairment (eGFR &lt;30 mL/min): NOT Recommended Severe hepatic impairment (Child-Pugh Class C): NOT recommended</td>
</tr>
<tr>
<td>Molnupiravir (Merck)</td>
<td>N/A</td>
<td>N/A</td>
<td><strong>Dose:</strong> 800mg molnupiravir (#4 200mg tablets) ORALLY twice daily for 5 days (No renal or hepatic dosing restrictions)</td>
</tr>
</tbody>
</table>
Outpatient Therapeutics
Provider and Patient EUA Fact Sheets

- Each product under EUA also has an FDA fact sheet for providers and one for patients and caregivers
  - bamlanivimab and etesevimab
    - Bamlanivimab and etesevimab provider fact sheet: https://www.fda.gov/media/145802/download
    - Bamlanivimab and etesevimab Patient fact sheet: https://www.fda.gov/media/145803/download
  - casirivimab and imdevimab (REGEN-COV)
    - Casirivimab and imdevimab Provider fact sheet: https://www.fda.gov/media/145611/download
    - Casirivimab and imdevimab Patient fact sheet: https://www.fda.gov/media/145612/download
  - sotrovimab
    - Sotrovimab Provider fact sheet: https://www.fda.gov/media/149534/download
    - Sotrovimab Patient fact sheet: https://www.fda.gov/media/149533/download
  - tixagevimab and cilgavimab (Evusheld)
    - Tixagevimab and cilgavimab Provider fact sheet: https://www.fda.gov/media/154701/download
    - Tixagevimab and cilgavimab Patient fact sheet: https://www.fda.gov/media/154702/download
Outpatient Therapeutics
Provider and Patient EUA Fact Sheets

- Each product under EUA also has an FDA fact sheet for providers and one for patients and caregivers
  - **Paxlovid**
    - Paxlovid provider fact sheet: https://www.fda.gov/media/155050/download
    - Paxlovid patient fact sheet: https://www.fda.gov/media/155051/download
    - Paxlovid patient fact sheet (Spanish): https://www.fda.gov/media/155075/download
  - **Molnupiravir**
    - Molnupiravir provider fact sheet: https://www.fda.gov/media/155054/download
    - Molnupiravir patient fact sheet: https://www.fda.gov/media/155055/download
    - Molnupiravir patient fact sheet (Spanish): https://www.fda.gov/media/155115/download
3. Overview of Outpatient Therapeutic Distribution Process
Principles for USG allocation and distribution

1. Maximize use of existing infrastructure within USG, as well as manufacturer and distributor channels.

2. Allocations must ensure both *temporal* and *geographic* equity.

3. USG to allocate to state and territorial health departments based on:
   - Confirmed Hospitalizations (7-Day Incident)
   - Confirmed Cases (7-Day Incident)

4. States/Territories responsible for distribution to administration sites.

5. Sites required to report product utilization.

6. Manufacturer tracks pharmacovigilance and follows mandatory reporting guidance.
Sites administering/dispensing USG-purchased COVID-19 therapeutics must provide information on product utilization and stock on hand.

**For bam/ete, sotrovimab, REGEN-COV**

- Long Term Care / Skilled Nursing Facilities
  - NHSN
- Hospitals / Hospital Pharmacies
  - HHSProtect/TeleTracking/Health Departments
- Non-hospital Facilities
  - HHS TeleTracking

Reporting required by 11:59 pm each Wednesday

**For Evusheld, Paxlovid, molnupiravir**

- Reporting required by 11:59 pm daily

- Reporting required by 11:59 pm daily
4. Monoclonal Antibody Administration
4. Monoclonal Antibody Administration: Site and Patient Logistics
Monoclonal Antibody Administration Can Occur Across a Wide Variety of Models

**Hospital**
- Hospital-based infusion centers
- Emergency departments
- Urgent care/Obs units/Fast track areas
- Converted space within hospital for COVID infusion
- Alternate care sites

**Ambulatory center**
- Infusion centers
- Urgent care clinics
- Dialysis centers
- Alternate care sites

**Nursing homes**
- Skilled nursing facilities
- Long-term care facilities

**Mobile sites**
- Bus/trailer
- Other mobile sites

**Home**
- At patient's home
Examples of staff plans (recommended positions may vary depending on the State’s scope of practice for Paramedics as it related to Subcutaneous and or Intravenous administration of medications or mAbs)

• 8-10 bed mAb infusion/observation site
  ▪ 1 physician / advanced practitioner (present or available via telemedicine)
  ▪ 2 Nurses
  ▪ 1 Nurse or Paramedic
  ▪ 2 Paramedics
  ▪ 1 flex position – administrative/ logistics/ runner

• Single station or mobile visit Subcutaneous administration site
  ▪ 1 physician / advanced practitioner (present or available via telemedicine)
  ▪ 1 Nurse / Paramedic per single mobile visit or single station

Average patient (door to door) visit can range from 80-120 minutes
Site Preparation

• Collect administration site location(s), address, and points of contact
  ▪ For mobile or deployed teams, identify the point of contact at the administration site and make contact
  ▪ Site will need dedicated space for isolation of COVID-19 patients¹
  ▪ Rededication of existing clinical space is permitted under the CMS Hospital Without Walls Initiative

• Ensure a patient scheduling and referral process is in place

• Identify and understand which therapeutics will be administered

• Determine who is responsible for ordering the monoclonal antibody administration
  ▪ Referring provider
  ▪ On-site or telemedicine provider
  ▪ Standing order

• Brief administration team with site objectives

• Team training
  ▪ Site workflow
  ▪ Monoclonal administration
  ▪ Managing adverse reactions with rescue medications on site as applicable

¹ Select recommendations for outpatient setting, for more information reference CDC guidelines
4. Monoclonal Antibody Administration: *Patient Pathways to Monoclonal Administration*
Pathway to Monoclonals: Patient with Confirmed COVID-19 Infection

- Treatment likely most beneficial to patients if given **early in symptom progression**
- EUA requires administration of **treatment as soon as possible after** confirmed positive test result and within **10 days of symptom onset**
- Strong **partnership and communication** between patients and HCP to get right treatment to right patients at right time
- Fast testing turnaround needed, to efficiently **identify positive tests** and **schedule for treatment**

Example of timeline which would fulfill EUA requirements

- **Onset of symptoms**
- **Clinical visit and diagnostic test** ≤ 3 days post symptom onset
- **Confirmed positive test** ≤ 24 hours post diagnostic test
- **Treatment ASAP post positive test result**

Treatment required within 10 days of symptom onset

Testing sites should recommend COVID+ patients that are high risk confer with their HCP on potential suitability for Tx

Please reference EUA factsheet for specific treatment guidelines including recommended treatment window

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Early administration of treatment needs **fast testing turn-around and patient scheduling**

Planning required for "Test and treat" or "Test and refer" models
Patient Flow for Outpatient mAbs Product

Scenario 1: Confirmed positive patient referred for treatment

**Pre-treatment**

Confirm documentation of COVID-19 infection via either
- Participant-provided lab report
- Medical record lab report
- Direct communication from a provider or laboratory

Discuss treatment with patient
- Ensure patient meets treatment requirements and understands risks

Schedule the patient to come in for treatment ASAP
- Provide guidance on site visit protocols to patients
- Provide patient education on what to expect with administration

*Pre-treatment steps should be completed via telemedicine as possible (~30 mins)*

**Treatment**

Pre-book time for administration space and follow clear protocol for coming onsite
- Ensure operationally ready to receive and treat the patient
- Use CDC recommended practices to minimize exposure to others

Provide treatment to patient
- Infusion duration up to ~1 hr\(^1\) with an additional 1 hr of observation post infusion (checks during infusion and observation)
- Infusion pumps or gravity-based infusion acceptable
- Subcutaneous administration if appropriate per EUA\(^2\)

Ensure preparation for administration reactions as unlikely but possible side effect
- Infusion rate may be reduced based on patient circumstances
- Ensure emergency action plan in place; ability to activate EMS if necessary, a requirement for administration under EUA

**Post-treatment**

Discharge patient immediately following monitoring completion
- Follow clear protocol to minimize risk of exposure to others

Post-treatment care encouraged to be via telemedicine as possible
- Normal follow-up care, no special data tracking requirements

---

1. Contingent on product dilution, reference EUA fact sheet for dilution and infusion timing
2. Reference EUA for route of administration
## Patient Flow for Outpatient mAbs Product

### Scenario 2 and 3: Patient arrives for testing at site with unknown diagnosis

### Pre-treatment

- **Direct patient to typical testing process for site (onsite or offsite)**
  - Quick response testing needed for early diagnosis to enable early treatment

- **Assuming patient discharged to await test results, once patient confirmed positive outreach on treatment (~30 mins):**
  - Discuss treatment with patient
    - Ensure patient meets treatment requirements and understands risks
    - Provide guidance on administration and site visit protocols to patients
  - Schedule the patient to come in for treatment ASAP
  - Pre-treatment discussion and scheduling should be via telemedicine as possible

### Treatment

- **Pre-book time for administration space and follow clear protocol for coming onsite**
  - Ensure operationally ready to receive and treat the patient
  - Use CDC recommended practices to minimize exposure to others

- **Provide treatment to patient**
  - Infusion duration up to ~1 hr\(^1\) with an additional 1 hr of observation post infusion (checks during infusion and observation)
  - Infusion pumps or gravity-based infusion acceptable
  - Subcutaneous administration if appropriate per EUA\(^2\)

- **Ensure preparation for administration reactions as unlikely but possible side effect**
  - Infusion rate may be reduced based on patient circumstances
  - Ensure emergency action plan in place; ability to activate EMS if necessary, a requirement for administration under EUA

### Post-treatment

- **Discharge patient immediately following monitoring completion**
  - Follow clear protocol to minimize risk of exposure to others

- **Post-treatment care encouraged to be via telemedicine as possible**
  - Normal follow-up care, no special data tracking requirements

---

1. Contingent on product dilution, reference EUA fact sheet for dilution and infusion timing
2. Reference EUA for route of administration
Patient Flow for Post-Exposure Prophylaxis

**Pre-treatment**

Confirm eligibility for PEP
- Patient meets CDC high risk exposure criteria
- Patient is not fully vaccinated or immunocompromised

Discuss treatment with patient
- Ensure patient meets treatment requirements and understands risks

Schedule the patient to come in for treatment ASAP
- Provide guidance on site visit protocols to patients
- Provide patient education on what to expect with administration

**Treatment**

Pre-book time for administration space and follow clear protocol for coming onsite
- Ensure operationally ready to receive and treat the patient
- Use CDC recommended practices to minimize exposure to others

Provide treatment to patient
- Infusion duration up to ~1 hr with an additional 1 hr of observation post infusion (checks during infusion and observation)
- Infusion pumps or gravity-based infusion acceptable
- Subcutaneous administration if appropriate per EUA

Ensure preparation for administration reactions as unlikely but possible side effect
- Infusion rate may be reduced based on patient circumstances
- Ensure emergency action plan in place; ability to activate EMS if necessary, a requirement for administration under EUA

**Post-treatment**

Discharge patient immediately following monitoring completion
- Follow clear protocol to minimize risk of exposure to others

Post-treatment care encouraged to be via telemedicine as possible
- Normal follow-up care, no special data tracking requirements

4. Monoclonal Antibody Administration: Team Roles and Responsibilities
Monoclonal Administration Site Team Members

• Administration Site Leadership
• Administrative personnel
• Clinical Team
  ▪ Composition dependent on state and local regulations and route of mAb administration (intravenous or subcutaneous)
  ▪ Medical Provider (MD/NP/PA) on-site or available via telemedicine
  ▪ Consider staff competence and comfort with IV insertion and management of pediatric patients if pediatric patients <40kg will be treated at the site
  ▪ Under an amendment to the PREP Act, Pharmacists and qualified Pharmacy Technicians may prescribe and administer COVID-19 therapeutics (subcutaneously, orally, or intramuscularly) unless otherwise stated in the product EUA¹

Monoclonal Antibody Administration Site Leadership

- Ensure ordering process is implemented
- Ensure required elements for administration are available
  - Personnel
  - Supplies
  - Administrative support
  - Identified site for administration
- Determination of scheduling process/logistics if treatment and PEP provided at the same site (as not all patients are COVID-positive)
- Determine mechanism for reimbursement of administration fees (product provided by the US Government is provided at no cost)
- Consider mechanism for interpreter services if patients are non-English speaking
- Delegate or perform administrative responsibilities
  - Direct ordering
  - Reporting of adverse events
  - Utilization reporting
Sites receiving monoclonal antibody will follow established mechanisms for tracking and reporting **serious adverse events**

- Events that are potentially attributable to monoclonal antibody use must be reported to the FDA
  - Refer to the Fact Sheet for Healthcare Providers as part of EUA for guidance
  - Complete and submit a MedWatch form or complete and fax FDA Form 3500 to report

Site must **maintain records** regarding use of the monoclonal antibody by patients

- **Inventory information**: e.g., lot numbers, quantity, receiving site, receipt date, product storage
- **Patient information**: e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered

Ensure that any records associated with this EUA are **maintained for inspection** upon request

Sites will report utilization weekly through the mechanism indicated by their local, state, or territorial health department
<table>
<thead>
<tr>
<th>Site of Care</th>
<th>Payable by Medicare</th>
<th>Expected Patient Cost-Sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Hospital</td>
<td>Yes</td>
<td>No patient cost-sharing</td>
</tr>
<tr>
<td>Outpatient Hospital or &quot;Hospital without Walls&quot;</td>
<td>Yes</td>
<td>No patient cost-sharing</td>
</tr>
<tr>
<td>Outpatient Physician Office/Infusion Center</td>
<td>Yes</td>
<td>No patient cost-sharing³</td>
</tr>
<tr>
<td>Nursing Home (See third bullet in Key Facts on CMS enforcement discretion)</td>
<td>Yes</td>
<td>No patient cost-sharing</td>
</tr>
<tr>
<td>Home</td>
<td>Yes</td>
<td>No patient cost-sharing</td>
</tr>
</tbody>
</table>

¹ Services must be furnished within the scope of the product’s FDA authorization or approval and within the provider’s scope of practice.
² Under the Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.
³ Cost-sharing may apply to Medicare beneficiaries when they receive care from a provider that doesn’t participate in Medicare.

**Expected Payment to Providers: Key Facts**

- Medicare payment for monoclonal antibody products to treat COVID-19 is similar across sites of care, with some small differences.

- Medicare pays for the administration of monoclonal antibody products to treat COVID-19. For example, Medicare will pay a national average of approximately $450 for the administration of certain monoclonal antibody products. Home infusion is reimbursed at a higher rate.

- CMS will exercise enforcement discretion to allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law to bill directly and receive direct reimbursement from the Medicare program for administering monoclonal antibody treatments to Medicare Part A Skilled Nursing Facility residents.

- Medicare will pay the provider for these monoclonal antibody products when they are purchased by the provider. Medicare won’t pay if the product is given to the provider for free by, for example, a government entity.

- When purchased by the provider, Medicare payment is typically at reasonable cost or at 95% of the Average Wholesale Price (an amount determined by the manufacturer). These payment amounts vary depending on which type of provider is supplying the product. Original Medicare will pay for these products for beneficiaries enrolled in Medicare Advantage.

- For more specific information about Medicare payments to providers for these monoclonal antibody products, please see these Frequently Asked Questions.

Regen-COV Product Codes

M0243:
• Long Descriptor: intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion and post administration monitoring

M0244:
• Long Descriptor: intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring in the home or residence

Bamlanivimab and Etesevimab Product Codes

M0245:
• Long Descriptor: intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring

M0246:
• Long Descriptor: intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence

Sotrovimab Product Codes

M0247:
• Long descriptor: intravenous infusion, sotrovimab, includes infusion and post-infusion monitoring

M0248:
• Long descriptor: intravenous infusion, sotrovimab, includes infusion and post-infusion monitoring in the home or residence

CMS.gov: Monoclonal Antibody COVID-19 Infusion – Monoclonal Antibody Products to Treat COVID-19
Ensure appropriate infection control practices in place based on latest CDC guidelines, e.g.:

- Have patient *wait to enter the site* until scheduled time for treatment
- Ensure patient *wearing a mask or face covering* before entering the building
- Escort patient *directly to room, limit transport and movement of the patient outside of the room*
- As all patients treated are confirmed positive for COVID-19, *multiple patients may be treated simultaneously in one area*.
- Medical and support personnel entering room need to *wear sufficient PPE* based on CDC guidelines
- Room should undergo *appropriate cleaning and surface disinfection* before it is returned to routine use

Select recommendations for outpatient setting for more information reference CDC guidelines: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
Clinical Team Responsibilities: Patient Intake

- If MD/NP/PA is on site, they can provide order for mAb after patient intake/screening completed

- Patient intake (healthcare provider type determined by state regulations/ scope of practice)
  - Ensure patient is **masked** for duration of encounter
  - Patient registration completed
  - Vital signs obtained (ensure patient does not require oxygen unless on home 02, therefore making them ineligible for mAb therapy and requiring escalation of care)
  - Eligibility criteria reviewed
    - Treatment eligibility criteria
    - Post exposure Prophylaxis Criteria
  - Patient Fact Sheet provided to patient prior to administration of mAb
Clinical Team Responsibilities

Monoclonal Administration

- mAb preparation for subcutaneous or intravenous administration
- Ensure patient privacy is maintained in accordance with HIPPA
- mAb administration
- Post-administration monitoring (60 minutes for all patients)
- Response to administration reaction
- Patient discharge and follow-up instructions
4. Monoclonal Antibody Administration: Indications and Administration
Indications for Monoclonal Therapy & Appropriate mAbs for Treatment

- **Pre-Exposure Prophylaxis in eligible persons**
  - EVUSHELD (tixagevimab and cilgavimab)

- **Active COVID-19 Infection in high risk individuals with mild to moderate symptoms**
  - Bamlanivimab and Etesevimab
  - REGEN-COV (casirivimab and imdevimab)
  - Sotrovimab

- **Post-Exposure Prophylaxis in vulnerable persons (i.e. not fully vaccinated or immunocompromised) who are at high risk for progression to severe COVID-19**
  - REGEN-COV (casirivimab and imdevimab)
  - Bamlanivimab and Etesevimab
Indications for Pre-Exposure Prophylaxis (PrEP)

- EVUSHELD (tixagevimab and cilgavimab)
EVUSHELD (tixagevimab and cilgavimab) is indicated for pre-exposure prophylaxis of COVID-19 in adults and pediatric (12 years of age and older and weighing at least 40kg):

• Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 AND

• who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination OR

• for whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and /or COVID-19 vaccine component(s)

*See Limitations of Authorized Use

Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab) (https://www.fda.gov/media/154701/download)
Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to¹:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm³, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

¹CDC Clinical Considerations for COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)
EVUSHELD (tixagevimab and cilgavimab) Pre-Exposure Prophylaxis: Limitations of Authorized Use

• Evusheld is not authorized for use in individuals:
  ▪ For treatment of COVID-19, or
  ▪ For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2

• Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination

• In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination

• EVUSHELD may only be prescribed by a healthcare provider licensed under State law to prescribe drugs for an individually identified patient and who has the education and training to make the clinical assessment necessary for appropriate use of EVUSHELD
EVUSHELD (tixagevimab and cilgavimab)
Preparation, Dose, & Administration

• Dose: tixagevimab 150mg and cilgavimab 150mg

• Administration
  ▪ Administer the two components sequentially
  ▪ Withdraw 1.5mL of tixagevimab and 1.5mL of cilgavimab solution into TWO separate syringes
  ▪ Administer the intramuscular (IM) injections at different injection sites, preferably one in each of the gluteal muscles, one after the other. The vastus lateralis is acceptable if gluteal injection is contraindicated
  ▪ The solutions for injection do not contain a preservative. Discard unused portion in accordance with local requirements
  ▪ As with any other IM injection, administer with caution to patients with thrombocytopenia or any coagulation disorder

• Observation: 60 minutes post-administration

• Storage: Refrigerate unopened vials at 2-8°C/36-46°F
Indications for Post-Exposure Prophylaxis (PEP)

- bamlanivimab and etesevimab**
- REGEN-COV (casirivimab and imdevimab)**

** Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

Bamlanivimab/etesevimab or casirivimab/imdevimab indicated for post-exposure prophylaxis of COVID-19 in individuals who are:

- Adult or pediatric (≥ 12 years of age and weighing at least 40kg) patient at high risk for progressing to severe disease or death (see high risk criteria) OR
- Pediatric Patient <40kg (including neonates)*** at high risk for progressing to severe disease or death (see high risk criteria) ***bamlanivimab/etesevimab only AND
- Not fully vaccinated¹ or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications²) AND
  - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC³ OR
  - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons) [see limitations of authorized use]

***Limitations of Authorized Use:

- Post-exposure prophylaxis with monoclonal antibody therapy is not a substitute for vaccination against COVID-19
- Bamlanivimab/etesevimab or casirivimab/imdevimab antibody therapy is not authorized for pre-exposure prophylaxis for prevention of COVID-19

1. CDC’s Have You Been Fully Vaccinated?
2. CDC’s Science Brief: COVID-19 Vaccines and Vaccination
3. CDC’s Quarantine and Isolation

**Not expected to retain activity against omicron variant
NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant
Individuals are considered to be **fully vaccinated** 2 weeks after their second vaccine dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as Johnson & Johnson’s Janssen vaccine). See this CDC website for more details on Have You Been Fully Vaccinated? (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html#vaccinated)

**CDC’s Science Brief: COVID-19 Vaccines and Vaccination**

Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). See this website for additional details on Quarantine and Isolation (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html)
Indications for Treatment of Patients with Confirmed COVID-19 Infection

- bamlanivimab and etesevimab**
- REGEN-COV (casirivimab and imdevimab)**
- sotrovimab

** Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

mAb Eligibility Criteria for TREATMENT of Mild-Moderate Covid-19 Infection in High Risk Adult and Pediatric (> 40kg) Patients

Mild to moderate COVID-19 cases early in infection, who are at high risk for progressing to severe COVID-19 and/or hospitalization; with following criteria:

• Adult or pediatric (≥ 12 years of age and weighing at least 40kg) patient
• Confirmation via positive PCR or antigen test
• Treatment as soon as possible following positive viral test and within 10 days of symptom onset
• Patient symptomatic but not yet progressed to require hospitalization or oxygen therapy (or increase from baseline chronic oxygen therapy)

Monoclonal antibodies given EUA for mild to moderate symptoms of COVID-19 are not authorized for use in patients:

• who are hospitalized due to COVID-19, OR
• who require oxygen therapy due to COVID-19, OR
• who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non- COVID-19 related comorbidity

Benefit of treatment with mAbs has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation
mAb Eligibility Criteria for TREATMENT of Mild-Moderate Covid-19 Infection in High Risk Pediatric Patients <40kg**

Mild to moderate COVID-19 cases early in infection, who are at high risk for progressing to severe COVID-19 and/or hospitalization; with following criteria:

- Neonate through pediatric and less than 40 kg
- Confirmation via positive PCR or antigen test
- Treatment as soon as possible following positive viral test and within 10 days of symptom onset
- Patient symptomatic but not yet progressed to require hospitalization or oxygen therapy (or increase from baseline chronic oxygen therapy)

Monoclonal antibodies given EUA for mild to moderate symptoms of COVID-19 are not authorized for use in patients:

- 2 years and older who are hospitalized due to COVID-19, OR

Regardless of age:

- who require oxygen therapy support due to COVID-19, OR
- who require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 in those on chronic oxygen therapy or respiratory support due to underlying non-COVID-19 related comorbidity

Benefit of treatment with mAbs has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

**Indicated therapeutic not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant
HIGH RISK FACTORS FOR TREATMENT AND POST-EXPOSURE PROPHYLAXIS WITH mAbs INCLUDE, BUT ARE NOT LIMITED TO:

- Older age (for example ≥ 65 years of age)
- Less than 1 year of age (bamlanivimab/etesevimab only)
- Obesity or being overweight (for example, adults with BMI ≥ 25, or if age 12-17, have BMI ≥ 85th percentile for their age and gender based on CDC growth charts)
- Pregnancy
- Chronic Kidney Disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital abnormalities)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and **authorization of mAb therapy is not limited to the medical conditions or factors listed above**. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, visit the CDC website:

- [CDC's Clinical Growth Charts](https://www.cdc.gov/growthcharts/clinical_charts.htm)
# Product Storage

<table>
<thead>
<tr>
<th>Product Storage</th>
<th>bamlanivimab/etesevimab</th>
<th>casirivimab/imdevimab</th>
<th>sotrovimab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Storage of UNOPENED VIALS in original carton</strong></td>
<td>Refrigerated (2-8°C/36-46°F): until expired</td>
<td>Refrigerated (2-8°C/36-46°F): until expired</td>
<td>Refrigerated (2-8°C/36-46°F): until expired</td>
</tr>
<tr>
<td></td>
<td>Room temperature (up to 25°C/77°F): 30 days</td>
<td>Room temperature (up to 25°C/77°F): 30 days</td>
<td></td>
</tr>
<tr>
<td><strong>Storage of PREPARED IV SOLUTION</strong></td>
<td>Refrigerated (2-8°C/36-46°F): 24 hours</td>
<td>Refrigerated (2-8°C/36-46°F): 36 hours</td>
<td>Refrigerated (2-8°C/36-46°F): 24 hours</td>
</tr>
<tr>
<td></td>
<td>Room temperature (20-25°C/68-77°F): 7 hours</td>
<td>Room temperature (up to 25°C/77°F): 4 hours</td>
<td>Room temperature (up to 25°C/77°F): 6 hours</td>
</tr>
<tr>
<td><strong>Storage of PREPARED SYRINGES</strong>**</td>
<td>n/a</td>
<td>Refrigerated (2-8°C/36-46°F): 24 hours</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Room temperature (up to 25°C/77°F): 8 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Time to Equilibrate to Room Temperature before Administration (Per EUA language)</strong></td>
<td>Approximately 20 minutes</td>
<td>30 minutes</td>
<td>Approximately 15 minutes</td>
</tr>
</tbody>
</table>

For most up to date information, refer to product EUA Fact Sheets:

**NOTE:** Temperature ranges and specifications are per each product EUA
mAb Preparation

Note: product can be prepared for infusion and subcutaneous administration bedside by any qualified medical professional

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

Needs for space to prepare mAb drug:
- Dedicated preparation area with sufficient capacity onsite or nearby

Acceptable equipment for mAb drug storage:
- Refrigerated storage (2-8° C)
- Temperature control mechanism including temperature monitoring process
- Storage area for REGEN-COV if stored at room temperature

Please see EUA manufacturer fact sheet for drug-specific requirements
General Guidelines for bamlanivimab/etesevimab Dosing, Dilution, & Administration: Adult and Pediatric (40+kg) Patients**

Table 1: Recommended Dilution and Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion³ in Adults (≥18 years regardless of weight) and Pediatric Patients (<18 years and weighing at least 40 kg)

<table>
<thead>
<tr>
<th>Size of Prefilled 0.9% Sodium Chloride Infusion Bag</th>
<th>Maximum Infusion Rate</th>
<th>Minimum Infusion Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mL</td>
<td>310 mL/hr</td>
<td>21 minutes</td>
</tr>
<tr>
<td>100 mL</td>
<td>310 mL/hr</td>
<td>31 minutes</td>
</tr>
<tr>
<td>150 mL</td>
<td>310 mL/hr</td>
<td>41 minutes</td>
</tr>
<tr>
<td>250 mL</td>
<td>310 mL/hr</td>
<td>60 minutes</td>
</tr>
<tr>
<td>For patients weighing at least 50 kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>250 mLb</td>
<td>266 mL/hr</td>
<td>70 minutes</td>
</tr>
<tr>
<td>For patients weighing ≥40 kg and &lt;50 kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant


General Guidelines for bamlanivimab/etesevimab Dosing & Administration: Pediatric Patients <40 kg (including neonates)

Table 2: Recommended Dosing, Preparation and Administration Instructions for Undiluted Bamlanivimab (BAM) and Etesevimab (ETE) for IV Infusion in Pediatric Patients (<18 years and weighing less than 40 kg)**

<table>
<thead>
<tr>
<th>Body Weight</th>
<th>BAM/ETE dose (mg)</th>
<th>Amount of BAM (as mL)a</th>
<th>Amount of ETE (as mL)a</th>
<th>Maximum Infusion Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;20 kg to &lt;40 kg</td>
<td>350 mg / 700 mg</td>
<td>10 mL</td>
<td>20 mL</td>
<td>1.88 mL/min</td>
</tr>
<tr>
<td>&gt;12 kg to 20 kg</td>
<td>175 mg / 350 mg</td>
<td>5 mL</td>
<td>10 mL</td>
<td>0.94 mL/min</td>
</tr>
<tr>
<td>&gt;11 kg to 12 kg</td>
<td>138 mg / 276 mg</td>
<td>3.9 mL</td>
<td>7.9 mL</td>
<td>0.74 mL/min</td>
</tr>
<tr>
<td>&gt;10 kg to 11 kg</td>
<td>126 mg / 252 mg</td>
<td>3.6 mL</td>
<td>7.2 mL</td>
<td>0.68 mL/min</td>
</tr>
<tr>
<td>&gt;9 kg to 10 kg</td>
<td>114 mg / 228 mg</td>
<td>3.3 mL</td>
<td>6.5 mL</td>
<td>0.61 mL/min</td>
</tr>
<tr>
<td>&gt;8 kg to 9 kg</td>
<td>102 mg / 204 mg</td>
<td>2.9 mL</td>
<td>5.8 mL</td>
<td>0.54 mL/min</td>
</tr>
<tr>
<td>&gt;7 kg to 8 kg</td>
<td>90 mg / 180 mg</td>
<td>2.6 mL</td>
<td>5.1 mL</td>
<td>0.48 mL/min</td>
</tr>
<tr>
<td>&gt;6 kg to 7 kg</td>
<td>78 mg / 156 mg</td>
<td>2.2 mL</td>
<td>4.5 mL</td>
<td>0.42 mL/min</td>
</tr>
<tr>
<td>&gt;5 kg to 6 kg</td>
<td>66 mg / 132 mg</td>
<td>1.9 mL</td>
<td>3.8 mL</td>
<td>0.36 mL/min</td>
</tr>
<tr>
<td>&gt;4 kg to 5 kg</td>
<td>54 mg / 108 mg</td>
<td>1.5 mL</td>
<td>3.1 mL</td>
<td>0.29 mL/min</td>
</tr>
<tr>
<td>&gt;3 kg to 4 kg</td>
<td>42 mg / 84 mg</td>
<td>1.2 mL</td>
<td>2.4 mL</td>
<td>0.23 mL/min</td>
</tr>
<tr>
<td>&gt;2 kg to 3 kg</td>
<td>30 mg / 60 mg</td>
<td>0.9 mL</td>
<td>1.7 mL</td>
<td>0.16 mL/min</td>
</tr>
<tr>
<td>&gt;1.5 kg to 2 kg</td>
<td>21 mg / 42 mg</td>
<td>0.6 mL</td>
<td>1.2 mL</td>
<td>0.11 mL/min</td>
</tr>
</tbody>
</table>

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

### casirivimab/imdevimab Formulations and Dose Preparation

**Dose: REGEN-COV (casirivimab 600mg and imdevimab 600mg)**

<table>
<thead>
<tr>
<th>Administration Route</th>
<th>Single Product Vials</th>
<th>REGEN-COV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intravenous</strong></td>
<td>casirivimab (REGN10933) <strong>5ml total</strong> (from 2.5 or 11.1 mL vials)</td>
<td><strong>10 mL total</strong></td>
</tr>
<tr>
<td>(Mixed and administered per EUA instructions)</td>
<td>imdevimab (REGN10987) <strong>5ml total</strong> (from 2.5 or 11.1 mL vials)</td>
<td></td>
</tr>
</tbody>
</table>

Intravenous infusion is strongly recommended for treatment of active infection. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment.

For Post-Exposure prophylaxis either subcutaneous injection or intravenous route can be used.

Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COVTM (casirivimab and imdevimab)

- Two syringes with 2.5 mL each of casirivimab (REGN10933) **(total of 5 ml casirivimab)**
- Two syringes with 2.5 mL each of imdevimab (REGN10987) **(total of 5 ml imdevimab)**
- Four syringes each containing 2.5mL REGEN-COV for a **total of 10mL**

**Not expected to retain activity against omicron variant**

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant
casirivimab and imdevimab Co-Packaged Cartons
(from Roche Pharmaceuticals)**

11.1 ML VIALS COPACK

- **1 VIAL OF CASIRIVIMAB**
  - 11.1 mL
  - NDC 61755-024-00

- **1 VIAL OF IMDEVIMAB**
  - 11.1 mL
  - NDC 61755-025-00

Although the carton is labeled “2 vials of 20 mL,” this is referring to the vial size and not the content of the vial. This presentation contains 2 vials of 11.1 mL (one of casirivimab and one of imdevimab).

This co-pack contains product for two patient courses

2.5 ML VIALS CO-PACK

- **1 VIAL OF CASIRIVIMAB**
  - 2.5 mL
  - NDC 61755-026-00

- **1 VIAL OF IMDEVIMAB**
  - 2.5 mL
  - NDC 61755-027-00

Although the carton is labeled “2 vials of 6 mL,” this is referring to the vial size and not the content of the vial. This presentation contains 2 vials of 2.5 mL (one of casirivimab and one of imdevimab).

Two cartons of this combination are required for one patient course

**Not expected to retain activity against omicron variant**

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

Utilizing REGEN-COV (casirivimab and imdevimab) Dose Pack**

Previously created REGEN-COV Dose Pack contains 2 patient courses as of the June 2021 EUA¹ (enclosed information sheet has dosing from prior EUA). 1 patient course is 5ml casirivimab/ 5ml imdevimab

The dose pack may be utilized for two doses. Once punctured, the vials should be discarded after 4 hours.

Refer to the “Regeneron Important Prescribing Letter” for more information

Please contact Regeneron Medical Affairs with any questions about using existing inventory to treat patients at 1-844-734-6643

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

Guidelines for REGEN-COV Repeat Dosing for Post-Exposure Prophylaxis**

- For individuals whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination.

- The initial dose is 600 mg of casirivimab and 600 mg of imdevimab by subcutaneous injection or intravenous infusion.

- Followed by subsequent repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by subcutaneous injection or intravenous infusion once every 4 weeks for the duration of ongoing exposure.

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

General Guidelines for REGEN-COV Intravenous Dosing, Dilution, and Administration**

Dilution Instructions for REGEN-COV (600 mg Casirivimab and 600mg Imdevimab) for intravenous infusion

<table>
<thead>
<tr>
<th>Size of Prefilled 0.9% Sodium Chloride Infusion Bag</th>
<th>Preparing Using Co-Formulated Casirivimab and Imdevimab Vial</th>
<th>Preparing Casirivimab and Imdevimab Using Individual Vialsa</th>
</tr>
</thead>
</table>
| 50 mL                                             | Add 10 mL of co-formulated Casirivimab and Imdevimab (1 vial) into a prefilled 0.9% sodium chloride infusion bag and administer as instructed below | Add:  
• 5 mL of Casirivimab (may use 2 vials of 2.5 ml OR 5 mL from 1 vial of 11.1 mL)  
• 5 mL of Imdevimab (may use 2 vials of 2.5 ml OR 5 mL from 1 vial of 11.1 mL)  
And inject into a prefilled 0.9% sodium chloride infusion bag and administer as instructed below. |
| 250 mL                                            |                                                            |                                                            |

Table 2: Recommended Administration Rate for Casirivimab and Imdevimab for Intravenous Infusion

<table>
<thead>
<tr>
<th>Size of Prefilled 0.9% Sodium Chloride Infusion Bag used</th>
<th>Maximum Infusion Rate</th>
<th>Minimum Infusion Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mL&lt;sup&gt;b&lt;/sup&gt;</td>
<td>180 mL/hr</td>
<td>20 minutes</td>
</tr>
<tr>
<td>100 mL</td>
<td>310 mL/hr</td>
<td>21 minutes</td>
</tr>
<tr>
<td>150 mL</td>
<td>310 mL/hr</td>
<td>31 minutes</td>
</tr>
<tr>
<td>250 mL</td>
<td>310 mL/hr</td>
<td>50 minutes</td>
</tr>
</tbody>
</table>

<sup>b</sup> The minimum infusion time for patients administered casirivimab and imdevimab together using the 50 mL prefilled 0.9% Sodium Chloride infusion bag must be at least 20 minutes to ensure safe use.

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) or REGEN-COVTM (casirivimab and imdevimab)
General Guidelines for REGEN-COV Subcutaneous Dosing and Administration

**Administration Instructions for REGEN-COV (600 mg Casirivimab and 600 mg Imdevimab) for subcutaneous injection**

<table>
<thead>
<tr>
<th>Prepare 600 mg of Casirivimab and 600 mg of Imdevimab</th>
<th>Preparation of 4 Syringes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Using Casirivimab and Imdevimab Co-formulated Vial</strong></td>
<td>Withdraw 2.5 mL solution per syringe into FOUR separate syringes.</td>
</tr>
</tbody>
</table>
| **Using Casirivimab and Imdevimab Individual Vials** | • Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes.  
• Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes.  
For total of 4 syringes. |

Preparation and Administration:

- Obtain four 3mL or 5mL luer lock syringes and four 21 gauge 1½ inch transfer needles.
- Withdraw 2.5 mL into each syringe per preparation instructions. **Prepare all four syringes at the same time.**
- Replace the 21 gauge transfer needle on each syringe with a 25-gauge or 27-gauge needle for subcutaneous injection.
- Administer the subcutaneous injections consecutively, **each at a different injection site**, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.
- **It is recommended that providers use different quadrants of the abdomen, upper thighs, or back of the upper arms to space apart each injection.**
- DO NOT inject into skin that is tender, damaged, bruised, or scarred.

Intravenous infusion is strongly recommended for treatment of active infection. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment.

For Post-Exposure Prophylaxis either subcutaneous or intravenous route can be used.

**Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab and imdevimab)**

**Not expected to retain activity against omicron variant**

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant
**REGEN-COV Subcutaneous Injection Sites**

- The prescribing healthcare provider and/or the provider’s designee are responsible for mandatory reporting of all medication errors and **ALL SERIOUS ADVERSE EVENTS** potentially related to REGEN-COV. These adverse events must be reported within seven calendar days from the onset of the event.

- Healthcare facilities and providers must report therapeutics information and demonstrate adequate utilization via data reported through HHS Protect, TeleTracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services.

- **MedWatch adverse event reports can be submitted to the FDA**, by submitting a postage-paid Form FDA 3500 and returning by mail/fax, or by calling 1-800-FDA-1088 to request a reporting form. In addition, please provide a copy of all FDA MedWatch forms to Regeneron Pharmaceuticals, Inc via fax (1-888-876-2736) or email (medical.information@regeneron.com).

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**Not expected to retain activity against omicron variant**

NIH COVID-19 Treatment Guidelines Panel’s Statement on SARS-CoV2 Monoclonal Antibodies or Remdesivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

General Guidelines for sotrovimab Dosing, Dilution, and Administration

Preparation

Sotrovimab is supplied in a single-dose vial and must be diluted prior to administration. Sotrovimab injection should be prepared by a qualified healthcare professional using aseptic technique.

- Gather the materials for preparation
  - Polyvinyl chloride (PVC) or polyolefin (PO), sterile prefilled infusion bag. Choose one of the following sizes:
    - prefilled 50-mL or 100 – mL infusion bag containing 0.9% Sodium Chloride Injection, and
    - One vial of sotrovimab (500 mg/8 mL).

- Remove one vial of sotrovimab from refrigerated storage and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes.
- Inspect the vial of sotrovimab visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded, and a fresh solution prepared.
  - Sotrovimab is a clear, colorless or yellow to brown solution

- Gently swirl the vial several times before use without creating air bubbles. Do not shake the vial.

- Withdraw 8 mL sotrovimab from one vial and inject into a prefilled infusion bag containing 0.9% Sodium Chloride Injection.

- Discard any product remaining in the vial.

- Prior to the infusion, gently rock the infusion bag back and forth by hand 3 to 5 times. Do not invert the infusion bag. Avoid forming air bubbles.

- This product is preservative-free; therefore, the diluted infusion solution should be administered immediately.
  - If immediately administration is not possible, store the diluted solution of sotrovimab up to 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) or refrigerated up to 24 hours (2°C to 8°C [36°F to 46°F]).

Administration

- Infuse over 30 minutes
- Do NOT deliver via IV push or IV bolus
- Monitor patient for 60 minutes after infusion

Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab
mAb Post-Administration Monitoring

- Per EUA, “Clinically monitor patients during dose administration and observe patients for at least 1 hour after intravenous infusion or subcutaneous dosing is complete”
- Provide education on follow-up, required isolation per CDC guidelines after COVID-19 exposure or diagnosis, red flags for seeking emergency care
- Respond to severe adverse events/ anaphylaxis
- “Discharge” patient after one hour post-administration monitoring if stable and without symptoms of severe adverse reaction
- Report any severe adverse events as required by the FDA through the process outlined in the EUA
4. Monoclonal Antibody Administration: Response to Adverse Events
Managing Adverse Reactions to mAbs

• Monoclonal antibodies may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion or hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

• Early identification of anaphylaxis. Symptoms may include:
  ▪ Respiratory: throat tightness, stridor, hoarseness, wheezing, respiratory distress, coughing, trouble swallowing/drooling, nasal congestion/drainage, sneezing
  ▪ Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain, cramps
  ▪ Cardiovascular: dizziness, fainting, tachycardia, hypotension, cyanosis, pallor, flushing
  ▪ Skin/mucosal: hives, erythema, itching, swelling of eyes, lips, tongue, mouth, face, or extremities
  ▪ Neurologic: agitation, convulsions, altered mental status, sense of impending doom
  ▪ Other: sudden increase in secretions, urinary incontinence
Managing Adverse Reactions to mAbs: Medications and Equipment

• **Should be available** at all sites:
  - Epinephrine (e.g., prefilled syringe or autoinjector)
  - H1 antihistamine (e.g., diphenhydramine, cetirizine)
  - Blood pressure monitor

• **If feasible**, include at sites (not required)
  - Oxygen
  - Bronchodilator (e.g., albuterol)
  - H2 antihistamine (e.g., famotidine, cimetidine)
  - Intravenous fluids
  - Intubation kit
  - Adult-sized pocket mask with one-way valve (CPR mask)

Adapted from [CDC Interim Considerations: Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites](https://www.cdc.gov/vaccines/covid-19/downloads/IntermConsid-Anaphylaxis-covid19-vaccine-sites.pdf)
Please note…
EUA guidelines continue to evolve

Please reference EUA fact-sheets for latest treatment guidelines and information, including:

- Therapeutic dosing
- Administration routes
- Dilution requirements and infusion time for intravenous or parenteral administration
COVID-19 Vaccination after mAb Administration

The current recommendation based on CDC guidance:

- Delay COVID-19 vaccine for 90 days after mAb for treatment of COVID-19 infection
- Delay COVID-19 vaccine for 30 days after mAb for post exposure prophylaxis

CDC Advisory Committee on Immunization Practices:

(Updated August 21, 2021)

People who previously received passive antibody therapy

Currently, there are limited data available on the safety and effectiveness of COVID-19 vaccines in people who received passive antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment or post-exposure prophylaxis. Based on the estimated half-life of such products and the anticipated period of protection against infection (when receiving anti-SARS-CoV-2 monoclonal antibodies for post-exposure prophylaxis) or reinfection (when receiving passive antibody therapy for treatment), COVID-19 vaccination should be temporarily deferred as a precautionary measure during the time period specified below after receiving passive antibody products to avoid potential interference of the product with vaccine-induced immune responses:

Passive antibody product used for post-exposure prophylaxis: defer COVID-19 vaccination for 30 days
Passive antibody product used for COVID-19 treatment: defer COVID-19 vaccination for 90 days

However, if passive antibody products and a COVID-19 vaccine dose are administered within these recommended deferral periods (30 or 90 days), the vaccine dose does not need to be repeated.

CDC’s Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

4. Monoclonal Antibody Administration: 
Supplies and Resources
Site Supplies Needed

Infrastructure
- Seating area with appropriate spacing for patients to receive mAb
- Steel table for product preparation
- Privacy screens if needed
- Protocol/outline for patient flow (written protocol not required however patient flow and infection control should be addressed at each administration site)
- Emergency response plan (written plan not required, however all staff should be aware of the plan for emergency response)

General supplies
- Infusion Reaction Kit
- Refrigerator
  - Optional to store prepared solution onsite
- Sharps container
- Biohazard disposal bag
- Trash bins and liners
- Disposable disinfecting wipes
- Hand sanitizer
- Thermometer probe covers (if required)
- 70% alcohol wipes
- Paper towels

PPE
- NIOSH-certified, disposable N95 filter facepiece respirators or better
- Gloves in appropriate sizes
- Gowns
- Surgical face masks for patients
- Eye and face protection (e.g. goggles, safety glasses, face shields)

Patient Intake
- Vital signs machine
- Pulse oximeter
- Thermometer
- Copies of eligibility checklist for treatment/ PEP

Administration Supplies- Subcutaneous
- Alcohol wipes
- 3 or 5mL luer lock syringes (4 required for each patient for subcutaneous administration)
- Appropriate needles for product preparation and subcutaneous administration
  - 21 gauge 1.5 inch needles for product transfer
  - 25 or 27 gauge needles for subcutaneous administration (4 per each patient course)

Administration Supplies- Intravenous
- IV poles
- Alcohol wipes
- 2x2 gauze pads
- Adhesive bandages
- Medical tape
- Tegaderm bio-occlusive dressing
- Absorbent underpads (blue pads)
- Normal saline bags for mixing/administration- 50-250 mL
- IV administration sets: PVC infusion set with/without DEHP containing 0.2 or 0.22 micron polyethersulfone (PES) in-line filter
- IV catheters
- IV extension set tubing
- 3mL saline syringes
- Needles – stainless steel 18ga
- Optional: Transilluminator (vein finder)
5. Oral Antiviral Administration
5. Oral Antiviral Administration: *Introduction to COVID-19 Oral Antiviral Therapies*
Paxlovid (Pfizer)

- FDA has issued an EUA for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults (12 years of age and older weighing more than 40kg) who are at high risk for progression to severe COVID-19, including hospitalization and death.

- Paxlovid includes: nirmatrelvir (a SARS-CoV-2 main proteases inhibitor) and ritonavir (a CYP34A inhibitor)

- Limitations of authorized use:
  - Not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19
  - Not authorized for use longer than 5 consecutive days

- PAXLOVID may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).

Fact Sheet for Health Care Providers Emergency Use Authorization of Paxlovid (https://www.fda.gov/media/155050/download)
Molnupiravir (Merck)

• Molnupiravir has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

• Not authorized for:
  - Patients less than 18 years of age
  - Initiation of treatment in patients requiring hospitalization due to COVID-19
  - Use longer than 5 consecutive days

• Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., anti-infectives).

Fact Sheet for Health Care Providers Emergency Use Authorization of Molnupiravir (https://www.fda.gov/media/155054/download)
# Oral Antiviral Indications and Dosing

<table>
<thead>
<tr>
<th>Antiviral Agent</th>
<th>PRE-EXPOSURE PROPHYLAXIS (PREP) for eligible individuals</th>
<th>POST-EXPOSURE PROPHYLAXIS (PEP) for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease</th>
<th>TREATMENT of Mild to Moderate within 5 days of symptom onset in patients with high risk or progression to severe disease</th>
</tr>
</thead>
</table>
| Paxlovid (Pfizer)       | N/A                                                      | N/A                                                                                | **Dose:**
|                         |                                                          |                                                                 | eGFR ≥60 ml/min: 300mg nirmatrelvir (#2 150mg tablets) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days |
|                         |                                                          |                                                                 | eGFR 30 to <60 mL: 150mg nirmatrelvir (#1 150mg tablet) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days |
|                         |                                                          |                                                                 | **Severe renal impairment (eGFR <30 mL/min):** NOT recommended |
|                         |                                                          |                                                                 | **Severe hepatic impairment (Child-Pugh Class C):** NOT recommended |
| Molnupiravir (Merck)    | N/A                                                      | N/A                                                                                | **Dose:** 800mg molnupiravir (#4 200mg tablets) ORALLY twice daily for 5 days |
|                         |                                                          |                                                                 | (No renal or hepatic dosing restrictions) |

Fact Sheet for Health Care Providers Emergency Use Authorization of Paxlovid (https://www.fda.gov/media/155050/download)
Fact Sheet for Health Care Providers Emergency Use Authorization of Molnupiravir (https://www.fda.gov/media/155054/download)
5. Oral Antiviral Administration: Prescriber Journey for Prescribing
Paxlovid Provider Checklist

- Positive SARS-CoV-2 test
- Age ≥12 years
- Weight ≥40 kg
- High-risk criteria met
- Symptoms consistent with mild-moderate COVID-19
- Symptom onset with 5 days*
- Not hospitalized due to COVID-19
- If clinically indicated, assess patient renal function
  - eGFR ≥60 mL/min, standard dosing
  - eGFR 30-60 mL/min, dose modification
  - eGFR <30 mL/min, contraindicated
- If clinically indicated, assess patient hepatic function
  - Child-Pugh Class C, contraindicated
- Assess patient’s home medication list for drug-drug interactions
  - See next slide for more detail

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating:
Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.
Contraindications

Hypersensitivity Reactions

- History of clinically significant hypersensitivity reactions (e.g., TEN, SJS) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product

Drugs highly dependent on CYP3A4 for clearance and for which elevated concentrations are associated with severe/life-threatening reactions*

- Alpha1-adrenergic receptor antagonists: alfuzosin
- Analgesics: pethidine, piroxicam, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio) when used for PAH
- Sedative/hypnotics: triazolam, oral midazolam

Drugs that are potent CYP3A4 inducers where significantly reduced nirmatrelvir or ritonavir concentrations are associated with loss of virologic response or resistance*

- Anticancer drugs: apalutamide
- Anticonvulsants: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal product: St John’s Wort (*hypericum perforatum*)

*NOT COMPLETE LIST OF ALL DDI’s. ALWAYS USE CLINICAL TOOLS/DDI CHECKER AND USE CLINICAL JUDGMENT
Molnupiravir Provider Checklist

- Positive SARS-CoV-2 test
- Age ≥18 years
- Alternate COVID-19 treatment options authorized by FDA are not accessible
- High-risk criteria met
- Symptoms consistent with mild-moderate COVID-19
- Symptom onset with 5 days*
- Not hospitalized due to COVID-19
- Assessment pregnancy and breastfeeding status (if applicable)
- Provide appropriate counseling
  - Females of childbearing potential treated: should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir
  - Breastfeeding is not recommended for the duration of treatment and for 4 days after the last dose of molnupiravir
  - Males of reproductive potential treated: if sexually active with females of childbearing potential, should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating:
Please fill prescription by __________[insert date]__________. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.
Molnupiravir Prescriber Requirements

All Patients

1. Provide electronic or hard copy of patient fact sheet
2. Document that patient has received an electronic or hard copy of the patient fact sheet
3. Review the information contained within the patient factsheet with the patient and counsel patient on the known and potential benefits and risks of MOV
4. Advise patients on need for contraception use as appropriate
   - Females of childbearing potential treated: should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir
   - Breastfeeding is not recommended for the duration of treatment and for 4 days after the last dose of molnupiravir
   - Males of reproductive potential treated: if sexually active with females of childbearing potential, should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose
5. The prescribing healthcare provider and/or the provider’s designee must report all medication errors and serious adverse events potentially related to molnupiravir within 7 calendar days from the healthcare provider’s awareness of the event
Molnupiravir Prescriber Requirements

Individuals of Childbearing Potential
1. Assess whether pregnant or not
   - Report of LMP in an individual who has regular menstrual cycles, uses a reliable method of contraception correctly and consistently or has had a negative pregnancy test
   - Negative pregnancy test (recommended but not required if other criteria are not met)
2. If pregnant:
   - Counsel the patient regarding the known and potential benefits and potential risks of molnupiravir use during pregnancy
   - Document that the patient is aware of the known and potential benefits and potential risks of molnupiravir use during pregnancy
   - Make the individual aware of the pregnancy surveillance program
   - If the pregnant individual agrees to participate in the pregnancy surveillance program and allows the prescribing healthcare provider to disclose patient specific information to Merck, the prescribing healthcare provider must provide the patient’s name and contact information to Merck (at 1-877-888-4231 or pregnancyreporting.msd.com)
3. If not pregnant:
   - Make the individual aware of the pregnancy surveillance program and encourage them to participate should they become pregnant
   - Review contraception requirements
4. How and where documentation occurs is at the discretion of the prescribing health care provider and their clinical site.
### Patient Flow for Antiviral Oral Therapies

**Scenario 1: Patient arrives at provider visit and medication available onsite**

<table>
<thead>
<tr>
<th>Visit with Provider</th>
<th>Visit Discharge</th>
<th>Post-visit</th>
</tr>
</thead>
</table>

**Confirm documentation of COVID-19 infection via either**
- Participant-provided lab report
- Medical record lab report
- Direct communication from a provider or laboratory

**Discuss treatment with patient**
- Ensure patient meets treatment requirements and understands risks

**Prescribe therapy for patient & provide the medication fact sheet**
- Document required patient assessment in medical record
- Provide patient education on medication therapy being prescribed.

*Pre-treatment steps should be completed via telemedicine as possible (~30 mins)*

**Medication and Fact Sheet provided to the patient**
- Ensure patient is understands medication therapy being provided
- Ensure medication therapy being dispensed complies with federal/state dispensing laws.

**Patient to begin prescribed therapy immediately and continue x 5 days**

**Patient to report any adverse effect to FDA Medwatch**
- Patients that present for hospital visit may continue their prescribed antiviral during hospitalization (at discretion of provider).
## Patient Flow for Antiviral Oral Therapies

**Scenario 2: Patient arrives at provider visit and medication NOT available onsite**

<table>
<thead>
<tr>
<th>Visit with Provider</th>
<th>Visit Discharge</th>
<th>Post-visit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Confirm documentation of COVID-19 infection via either</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Participant-provided lab report</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Medical record lab report</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Direct communication from a provider or laboratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Discuss treatment with patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Ensure patient meets treatment requirements and understands risks</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prescribe therapy for patient &amp; provide the medication fact sheet</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Document required patient assessment in medical record</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Provide patient education on medication therapy being prescribed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Determine locations medication is available in local area.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prescription and Fact Sheet provided to the patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Ensure patient is understands medication therapy being prescribed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Ensure patient is advised where to go pick up the medication therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pharmacy receives patient prescription</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pharmacy should prioritize the prescription fill and ensure timely turnaround to support same day start for therapy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pharmacist verifies prescription is appropriate for patient. Any concerns are clarified with prescribing provider.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pharmacy staff dispenses product to the patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient is counseled on medication therapy and reminded to start immediately.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient to begin prescribed therapy immediately and continue x 5 days</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient to report any adverse effect to FDA Medwatch</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patients that present for hospital visit may continue their prescribed antiviral during hospitalization (at discretion of provider).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. Oral Antiviral Administration: 
*Pharmacy Journey for Dispensing*
Pharmacy Journey

Pharmacy receives antiviral Rx (either product) for patient

Pharmacist reviews fill-by date to ensure Rx still valid

STOP:
No fill if outside 5-day therapeutic window & contact prescriber

Molnupiravir

Dispense prescribed product & Molnupiravir EUA Fact Sheet (if not provided by prescriber)

**If pharmacist has question regarding dosing/possible DDI/known contraindication, will need to contact prescriber same day in order to have minimal dispensing delay to patient (time-sensitive nature of drug)**

Paxlovid

Review patient chart for major drug interactions (if information available)

Review prescribed dosing for any required renal adjustment requirements prior to dispensing

Dispense prescribed product & Paxlovid EUA Fact Sheet (if not provided by prescriber)

Dispense prescribed product per EUA required renal dosing packaging requirements & Paxlovid EUA Fact Sheet (if not provided by prescriber)
Paxlovid Renal Adjustment Instructions for Pharmacists

**STEP 1:** remove one 150mg nirmatrelvir tablet from each dose of blister card (closet to middle)

**STEP 2:** affix blister card with one sticker from the provided tear pad to cover the blister cavities

**STEP 3:** repeat steps 1 and 2 for every blister card in the carton (total of 5)

**STEP 4:** affix one sticker from provided tear pad to cover the pre-printed dosing regimen (new dosing regimen for renal adjustment)
Paxlovid EUA Renal Adjustment Instructions for Pharmacists

Figure 1: Remove the nirmatrelvir tablets circled in red from the blister card

Figure 2: Placement of sticker over empty blister cavities and pre-printed dosing instruction after removal of nirmatrelvir tablets

Figure 3: Placement of sticker over pre-printed dosing regimen on carton
**CMS: Coverage of Oral Antiviral Therapies to Treat COVID-19**

### Medicare

<table>
<thead>
<tr>
<th>Site of Care</th>
<th>Payable by Medicare</th>
<th>Expected Patient Cost-Sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Hospital</td>
<td>✓</td>
<td>No patient cost-sharing</td>
</tr>
<tr>
<td>Outpatient Hospital or “Hospital without Walls”</td>
<td>✓</td>
<td>No patient cost-sharing</td>
</tr>
<tr>
<td>Outpatient Physician Office</td>
<td>✓</td>
<td>No patient cost-sharing³</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>✓</td>
<td>No patient cost-sharing</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>✓</td>
<td>No patient cost-sharing</td>
</tr>
</tbody>
</table>

1 Services must be furnished within the scope of the product’s FDA authorization or approval and within the provider’s scope of practice.

2 Under the Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.

3 Cost-sharing may apply to Medicare beneficiaries when they receive care from a provider that doesn’t participate in Medicare.

### Expected Payment to Providers: Key Facts

- CMS will provide a list of pharmacies that have provider agreements with the USG to dispense the drug in compliance with the terms and conditions of authorization. CMS will provide a list of these pharmacies, including National Provider Identifier (NPI), on the Health Plan Management Site as soon as it is available.

- Pay dispensing fees: While certain USG-procured oral antiviral drug(s) will be made available at no cost to pharmacies, the procurement does not include payment of a dispensing fee to pharmacies. CMS encourages Part D sponsors to pay a dispensing fee to pharmacies that submit claims for these drugs. No ingredient cost can be paid on these claims.

- Part D sponsors should not charge enrollee cost sharing on dispensing fees paid to the pharmacies.

- Sponsors should consult NCPDP Emergency Preparedness Guidance for “Billing for Reimbursement of a Free Product (No associated cost) with No Administration Fee” as they prepare to implement these changes.

- For more specific information about Medicare payments to providers for these monoclonal antibody products, please see these Frequently Asked Questions.

CMS Codes

- Molnupiravir Product Codes
  *NDC numbers: 0006-5055-06, NDC-0006-5055-07*

- Paxlovid Product Codes
  *NDC number: 0069-1085-06*

Continue to check CMS website for most up to date information: [www.CMS.gov](http://www.CMS.gov)

HRSA Coverage for Uninsured

*HRSA uninsured fund* (https://www.hrsa.gov/CovidUninsuredClaim)

[Emergency Use Authorization of Molnupiravir](https://www.fda.gov/media/155053/download)
[Emergency Use Authorization of Paxlovid](https://www.fda.gov/media/155049/download)
5. Oral Antiviral Administration: Patient Journey
Patient journey | Given need for treatment within 5 days of symptom onset, patient journey timeline should aim for rapid Rx access

- **Day 0**: Time between infection & test varies
- **Day X**: Rapid tests = same day results, Lab tests = 1-2 days
- **Goal is same day from test result to receiving Rx**
- **As fast as same day**
- **As fast as same day; Mitigation measures needed to ensure access to same day pickup / delivery**

1. Patient infected
2. Patient is tested and receives results of test
3. Patient is evaluated and prescribed treatment
4. Patient receives treatment

Note: If patient unvaccinated (or no booster) at time of oral antiviral treatment, patient may receive a COVID-19 vaccination once isolation/quarantine period completed.¹

¹ [CDC clinical considerations](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination)
**Patient journey | Overview of patient journey for oral antivirals based on testing channel**

1. **Patient infected**
   - Patient infected (with/without symptoms)
   - Patient decides to get tested (symptoms/exposure)

2. **Patient is tested and receives results of test**
   - Patient tested with either rapid or lab test
   - Patient receives results

3. **Patient is evaluated and prescribed treatment**
   - Patient seeks treatment, makes appointment, and is evaluated by provider
   - Provider issues Rx if patient eligible
   - Patient educated on Tx options

4. **Patient receives treatment**
   - Pharmacy/clinic dispenses Rx to patient

**Common steps across most patient journeys**
- Patient infected (with/without symptoms)
- Patient decides to get tested (symptoms/exposure)
- Patient tested with either rapid or lab test
- Patient receives results
- Patient seeks treatment, makes appointment, and is evaluated by provider
- Provider issues Rx if patient eligible
- Patient educated on Tx options
- Pharmacy/clinic dispenses Rx to patient

**Different channels where test occurs:**

<table>
<thead>
<tr>
<th>Channel</th>
<th>Patient infected (with/without symptoms)</th>
<th>Patient tested with either rapid or lab test</th>
<th>Patient seeks treatment, makes appointment, and is evaluated by provider</th>
<th>Pharmacy/clinic dispenses Rx to patient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Retail Rx site</strong></td>
<td>Patient may also test due to regular screening</td>
<td>Patient locates, makes appointment, travels to retail pharmacy</td>
<td>If clinic/prescriber is available at Retail site, potential for patient to seek care on-site</td>
<td>Patient locates Pharmacy if using one different than retail site</td>
</tr>
<tr>
<td><strong>Outpatient clinic</strong></td>
<td>No variation to common steps</td>
<td>Patient locates, may make appointment, travels to ER/urgent care/other HCP office</td>
<td>Patient may see same or different provider for evaluation as they did for testing</td>
<td>Patient locates Pharmacy or dispensed at point of care</td>
</tr>
<tr>
<td><strong>Patient's Home</strong></td>
<td>No variation to common steps</td>
<td>Patient locates then orders/picks up at home test</td>
<td>No variation to common steps</td>
<td>Patient locates Pharmacy or dispensed at point of care</td>
</tr>
<tr>
<td><strong>Temp. testing site</strong> (e.g., mass testing)</td>
<td>No variation to common steps</td>
<td>Patient locates, travels to site</td>
<td>No variation to common steps</td>
<td>Patient locates Pharmacy or dispensed at point of care</td>
</tr>
</tbody>
</table>

Non-exhaustive list – many other patient journeys exist
6. Additional Resources
Oral Antiviral Therapies

Paxlovid Product Information

Molnupiravir Product Information
https://www.molnupiravir-us.com/
Other Oral Antiviral Resources

Paxlovid
- Paxlovid Provider fact sheet https://www.fda.gov/media/155050/download
- Paxlovid Patient fact sheet https://www.fda.gov/media/155051/download
- Paxlovid Patient fact sheet (Spanish) https://www.fda.gov/media/155075/download

Molnupiravir
- Molnupiravir Provider fact sheet https://www.fda.gov/media/155054/download
- Molnupiravir Patient fact sheet https://www.fda.gov/media/155055/download
- Molnupiravir Patient fact sheet (Spanish) https://www.fda.gov/media/155115/download

Submit adverse event and medication error reports to FDA MedWatch using one of the following methods:
- Online: https://www.fda.gov/medwatch/report.htm
- Complete and submit a postage-paid FDA Form 3500 and returning by mail/fax
- Call 1-800-FDA-1088 to request a reporting form

Centers for Disease Control and Prevention: Healthcare Workers Information on COVID-19
Product-Specific Sites for Monoclonal Antibody Administration

Provides additional detail on administration of etesevimab and bamlanivimab
https://www.covid19.lilly.com/bam-ete/hcp

Provides additional detail on administration of REGEN-COV (casirivimab and imdevimab)
https://www.regencov.com/hcp

Provides additional detail on administration of sotrovimab
https://www.sotrovimab.com

Provides additional detail on administration of Evusheld (tixagevimab co-packaged with cilgavimab)
https://www.evusheld.com
Helpful Links

- **Federal Monoclonal Antibody Site**
  - [https://www.phe.gov/mAbs](https://www.phe.gov/mAbs)

- **PHE COVID-19 Toolkit**
  - [https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/toolkit.aspx](https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/toolkit.aspx)

- **CMS Hospital Without Walls**

- **CMS Monoclonal Antibody Reimbursement**

- **CDC COVID Data Tracker**

- **Clinical Trial Information for Patients not Eligible for EUA**
  - **Lilly Clinical Trials**
  - **Regeneron Clinical Trials**
    - [https://www.regeneron.com/covid19](https://www.regeneron.com/covid19)
Helpful Resources for Clinicians

- **COVID-19 Outpatient Therapies Side-by-Side Overview**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/Side-by-Side-Overview-of-mAbs-Treatment.aspx

- **Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints**

- **Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19**

- **COVID-19 Monoclonal Antibody Eligibility Checklist: Treatment and PEP**

- **COVID-19 Monoclonal Antibody Checklist for Subcutaneous and Intravenous Administration**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/covid19-mAb-checklist-subcutaneous-intravenous-administration.aspx
Helpful Resources for Clinicians continued

• **Subcutaneous Injection Instructions**

• **EMS Template Protocol**

• **Guidelines on Vaccination after mAb administration**
| Educational Opportunities: Project Echo Sessions on Monoclonal Antibodies |

<table>
<thead>
<tr>
<th>Topic</th>
<th>Date</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monoclonal Antibodies - Bamlanivimab</td>
<td>2/9/2020</td>
<td><a href="https://www.youtube.com/watch?v=YKjRgQGl-Nw">https://www.youtube.com/watch?v=YKjRgQGl-Nw</a></td>
</tr>
<tr>
<td>Equitable Access - Outpatient Infusion Site</td>
<td>2/16/2020</td>
<td><a href="https://www.youtube.com/watch?v=0ZZixudBeog">https://www.youtube.com/watch?v=0ZZixudBeog</a></td>
</tr>
<tr>
<td>Monoclonal Antibodies: OSU experience</td>
<td>12/3/2020</td>
<td><a href="https://www.youtube.com/watch?v=p3Jsr9wasEU">https://www.youtube.com/watch?v=p3Jsr9wasEU</a></td>
</tr>
<tr>
<td>Where are we now? mAb Therapy in Michigan</td>
<td>1/6/2021</td>
<td><a href="https://www.youtube.com/watch?v=CnnyiMayiXc">https://www.youtube.com/watch?v=CnnyiMayiXc</a></td>
</tr>
<tr>
<td>Monoclonal antibodies: A Healthcare system’s approach (mAb Treatment at Mass General)</td>
<td>1/13/2021</td>
<td><a href="https://hsc.unm.edu/echo/_docs/hhs-covid/rajgandhi1.13.21-monoclonalantibodies-.pdf">https://hsc.unm.edu/echo/_docs/hhs-covid/rajgandhi1.13.21-monoclonalantibodies-.pdf</a></td>
</tr>
<tr>
<td>• Presentation by Rajesh T. Gandhi, MD</td>
<td></td>
<td><a href="https://hsc.unm.edu/echo/_docs/hhs-covid/1.13.21-hhs-mab-lennes.pdf">https://hsc.unm.edu/echo/_docs/hhs-covid/1.13.21-hhs-mab-lennes.pdf</a></td>
</tr>
<tr>
<td>• Presentation by Inga T. Lennes MD, MPH,MBA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managing infusion reactions Northwell Health Experience</td>
<td>1/27/2021</td>
<td><a href="https://www.youtube.com/watch?v=zaem2mDUvKE">https://www.youtube.com/watch?v=zaem2mDUvKE</a></td>
</tr>
<tr>
<td>EMS involvement in mAb infusion programs</td>
<td>2/1/2021</td>
<td><a href="https://www.youtube.com/watch?v=CZnCv4kttnmw">https://www.youtube.com/watch?v=CZnCv4kttnmw</a></td>
</tr>
<tr>
<td>Achieving Speed and Scale in FQHCs and Health Systems</td>
<td>2/10/2021</td>
<td><a href="https://hsc.unm.edu/echo/_docs/hhs-covid/2.10.21-manini.pdf">https://hsc.unm.edu/echo/_docs/hhs-covid/2.10.21-manini.pdf</a></td>
</tr>
<tr>
<td>• Presentation by Corinna Manini, MD</td>
<td></td>
<td><a href="https://hsc.unm.edu/echo/_docs/hhs-covid/2.10.21-webb.pdf">https://hsc.unm.edu/echo/_docs/hhs-covid/2.10.21-webb.pdf</a></td>
</tr>
<tr>
<td>• Presentation by Brandon Webb, MD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regional Approaches to mAb Administration-Operationalizing Partnerships</td>
<td>2/17/2021</td>
<td><a href="https://www.youtube.com/watch?v=h-ewtgAO1gl">https://www.youtube.com/watch?v=h-ewtgAO1gl</a></td>
</tr>
<tr>
<td>Equity and Underserved Populations</td>
<td>2/24/2021</td>
<td><a href="https://www.youtube.com/watch?v=lGeh2hSImQ">https://www.youtube.com/watch?v=lGeh2hSImQ</a></td>
</tr>
<tr>
<td>Clinical trials update and Patient/Provider Outreach</td>
<td>3/3/2021</td>
<td><a href="https://www.youtube.com/watch?v=7AHSUqC5tWc">https://www.youtube.com/watch?v=7AHSUqC5tWc</a></td>
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<tr>
<td>Partnering with Urgent Care Centers to Increase Access and Utilization of COVID mAbs: NYC Health</td>
<td>3/10/2021</td>
<td><a href="https://www.youtube.com/watch?v=tDTVZy7FDe4">https://www.youtube.com/watch?v=tDTVZy7FDe4</a></td>
</tr>
<tr>
<td>Where We’re Headed: Variants and COVID-19 Therapy</td>
<td>3/24/2021</td>
<td><a href="https://www.youtube.com/watch?v=edPa0ZLmeR">https://www.youtube.com/watch?v=edPa0ZLmeR</a></td>
</tr>
<tr>
<td>Real world effectiveness and implementation of COVID-19 monoclonal antibodies</td>
<td>4/22/2021</td>
<td><a href="https://www.youtube.com/watch?v=s2ktIgL4uJ4">https://www.youtube.com/watch?v=s2ktIgL4uJ4</a></td>
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For information on upcoming sessions visit: HHS ASPR Clinical Rounds
Questions?
https://phe.gov/mAbs
Email: covid19therapeutics@hhs.gov

Thank you!