CDC/IDSA COVID-19 Clinician Call
January 8, 2022

Welcome & Introductions
Dana Wollins, DrPH, MGC
Vice President, Clinical Affairs & Guidelines IDSA

• 82nd in a series of bi-weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19. This call is not intended for the media.

• The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

• This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
COVID-19 Treatment Updates Plus the Latest on Omicron

Update on the Omicron Variant
CAPT Lauri Hicks, DO
Chief Medical Officer, CDC COVID-19 Response
US Centers for Disease Control and Prevention

Recent FDA Updates & Authorizations
John Farley, MD, MPH
Director of the Office of Infectious Diseases
Office of New Drugs
U.S. Food and Drug Administration

Allocation & Distribution of COVID-19 Therapeutics
Colin W. Shepard, MD
Medical Officer
U.S. Department Of Health and Human Services
CDC Liaison to the Office of the Assistant Secretary for Preparedness and Response
U.S. Centers for Disease Control and Prevention

Clinical Considerations
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Director, HIV Clinical Services and Education
Massachusetts General Hospital
Co-Director, Harvard Center for AIDS Research
Professor of Medicine, Harvard Medical School

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Sarah H. Sell and Cornelius Vanderbilt Professor
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Department of Pediatrics
Vanderbilt University Medical Center

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Director of Clinical Research, Division of Infectious Diseases
Brigham and Women's Hospital
Director, Infectious Diseases, Dana-Farber Cancer Institute

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Senior Clinical Instructor
Case Western Reserve University, School of Medicine

Jason Gatiliff, PhD
Integrated Ethics Program Officer
VA Northeast Ohio Healthcare System
Update on the Omicron Variant

CAPT Lauri Hicks, DO
Update on the Omicron Variant

CAPT Lauri Hicks, DO
Chief Medical Officer
CDC COVID-19 Response
January 8, 2022
What are the key questions we’re trying to answer?

- How **transmissible** is Omicron?
- How **severe** is Omicron compared to other variants?
- How well do vaccines and prior infection **protect** against infection, transmission, clinical disease, and death due to Omicron?

https://www.who.int/publications/m/item/enhancing-readiness-for-omicron-(b.1.1.529)-technical-brief-and-priority-actions-for-member-states
Transmissibility
COVID-19 cases rapidly increased since the first U.S. Omicron case was reported on December 1, 2021.

57,898,239
Total Cases Reported
705,264
New Cases Reported**
586,391
Current 7-Day Average**
Dec 30, 2021 - Jan 05, 2022
315,851
Prior 7-Day Average**
Dec 23, 2021 - Dec 29, 2021
85.7%
Change in 7-Day Average

*Graph displays data for Mar 01, 2020, to date. The totals include cases reported since Jan 22, 2020.
** The histogram, total of new cases in the last 24 hours, and 7-day averages do not include historical cases retroactively that are not yet attributed to the correct date of report. Of 352,811 historical cases reported retroactively, none were reported on the most recent submission date: 134 in the current week; and 621 in the prior week.
The proportion of COVID-19 cases due to Omicron is increasing.

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates.
Data suggest higher household transmissibility of Omicron compared with Delta among vaccinated persons (Denmark, 2021).

<table>
<thead>
<tr>
<th></th>
<th>Omicron households (N=2225)</th>
<th>Delta households (N=9712)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2° attack rate (# 2° cases)</td>
<td>Odds ratio for transmissibility (95% CI)</td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>29% (340)</td>
<td>1.04 (0.87-1.24)</td>
</tr>
<tr>
<td>Fully vaccinated</td>
<td>32% (1057)</td>
<td>ref</td>
</tr>
<tr>
<td>Booster-vaccinated</td>
<td>25% (77)</td>
<td>0.54 (0.40-0.71)</td>
</tr>
</tbody>
</table>

SARS-CoV-2 Omicron VOC Transmission in Danish Households (medrxiv.org)
Severity
U.S. hospitalizations with confirmed COVID-19 are surpassing peaks from last winter.

3,773,704
Total New Admissions
Aug 01, 2020 – Jan 04, 2022

19,232
New Admissions
Jan 04, 2022

16,458
Current 7-Day Average
Dec 29, 2021 – Jan 04, 2022

10,271
Prior 7-Day Average
Dec 22, 2021 – Dec 28, 2021

+60.2%
Change in 7-Day Average

-0.2%
Change Since Peak 7-Day Average

In South Africa, patients admitted during the Omicron wave were 73% less likely to have severe disease than those admitted during the Delta wave.

Clinical Severity of COVID-19 Patients Admitted to Hospitals in Gauteng, South Africa During the Omicron-Dominant Fourth Wave by Waasila Jassat, Salim Abdool Karim, Caroline Mudara, Richard Welch, Lovelyn Ozougwu, Michelle Groome, Nevashan Govender, Anne von Gottberg, Nicole Wolter, DATCOV Author Group, Lucille Blumberg, Cheryl Cohen :: SSRN
Hospitalization rates have been relatively lower during the Omicron wave in multiple countries.

- Hospitalization rates for persons infected with Omicron: 0.4% in United Kingdom, and 0.6% in Denmark
- Risk of hospitalization due to Omicron infections estimated to be 38% (England) and 54% (Canada) lower than hospitalization for Delta infections

Omicron daily overview: 30 December 2021 (publishing.service.gov.uk)
rapport-omikronvarianten-29122021-ub46 (ssi.dk)
Early estimates of SARS-CoV-2 Omicron variant severity based on a matched cohort study, Ontario, Canada | medRxiv
Vaccine Effectiveness
Neutralization of the Omicron variant is reduced compared with ancestral and Delta strains.

<table>
<thead>
<tr>
<th>Sera from persons with different vaccination and infection scenarios</th>
<th>Time of collection after last vaccine dose</th>
<th>Neutralization of Omicron and range reduction compared with ancestral and Delta strains</th>
<th>References</th>
</tr>
</thead>
</table>
Pfizer mRNA vaccine effectiveness (VE) is lower for symptomatic infection due to Omicron compared to Delta.

- **Post 2-dose**: increased waning immunity for Omicron (~15%) vs. Delta (~60%) at 25+ weeks post 2\textsuperscript{nd} dose
- **Booster**: ~65% VE against Omicron 2 weeks; decreases to 45% at 10+ weeks
Preparedness
Prevention strategies are key to increasing protection against the Omicron variant.

- Vaccination
  - Recommended for everyone ages ≥5 years
  - Booster eligibility expanded to all persons ages ≥12 years
    - ≥2 months after initial Janssen vaccine
    - ≥5 months for individuals who have completed a Pfizer-BioNTech or Moderna primary series
  - Additional dose authorized for immunocompromised children ages 5-11 years

- Increased emphasis on the importance of masking
- Improved ventilation
- Wider and more frequent testing, including self-testing
- Adherence to guidance on quarantine and isolation

https://www.cdc.gov/mmwr/volumes/70/wr/mm7050e1.htm?s_cid=mm7050e1_w
CDC released new isolation and quarantine guidance.

Summary

- Accumulating evidence suggests that the Omicron variant is more transmissible but causes less severe disease.

- Currently authorized vaccines offer less protection against infection due to Omicron compared to ancestral strains and previous variants but still provide benefit—important to increase uptake of primary vaccination and boosters in eligible populations to optimize protection.

- CDC is closely monitoring real-world vaccine effectiveness and breakthrough infections using multiple methods, populations, and outcomes.

- Layered prevention strategies are key for minimizing the impact of the spread of the Omicron variant.
For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Recent FDA Updates & Authorizations

John Farley, MD, MPH
Recent FDA Updates and Authorizations

John Farley, MD, MPH
Director, Office of Infectious Diseases
Office of New Drugs,
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Monoclonal Antibody Fact Sheets Updated with Virology Information for Omicron

<table>
<thead>
<tr>
<th>Casirivimab and Imdevimab Together (REGEN-COV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.1.529/BA.1 Omicron</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Bamlanivimab and Etesevimab Together</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.1.529/BA.1 Omicron</td>
</tr>
</tbody>
</table>
Monoclonal Antibody Fact Sheets Updated with Virology Information for Omicron

| Sotrovimab | B.1.1.529/BA.1 Omicron | G339D+S371L+S373P+S375F+K417N+N440K+G446S+S477N+T478K+E484A+Q493R+G496S+Q498R+N501Y+Y505H | Pseudotyped Virus-Like Particle Neutralization Data | No change (<5 - fold reduction in susceptibility) |

• Casirivimab and imdevimab together are unlikely to be active against variants from this lineage.
• Bamlanivimab and etesevimab together are unlikely to be active against variants from this lineage.
• Healthcare providers should choose an authorized therapeutic option with activity against the circulating variants in their state, territory, or US jurisdiction. Current variant frequency data are available at: [https://covid.cdc.gov/covid-data-tracker/#variant-proportions](https://covid.cdc.gov/covid-data-tracker/#variant-proportions)
EVUSHELD™ Authorization for PrEP

- Tixagevimab co-packaged with cilgavimab, SARS-CoV-2 spike protein-directed attachment inhibitor.

**Authorization:** for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- 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 COVID19 vaccine component(s)
EVUSHELD™ – Clinical Considerations

• Not authorized for treatment of COVID-19, nor 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.

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

• Examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination are provided in the Health Care Provider Fact Sheet.

Health Care Provider Fact Sheet: https://www.fda.gov/media/154701/download
# EVUSHELD™ Fact Sheet Updated with Virology Information for Omicron

<table>
<thead>
<tr>
<th>Tixagevimab and cilgavimab together</th>
<th>B.1.1.529/BA.1 Omicron</th>
<th>Authentic Virus</th>
<th>12* to 30 - fold reduction in susceptibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>G339D+S371L+S373P+S375F+K417N+N440K+G446S+S477N+T478K+E484A+Q493R+G496S+Q498R+N501Y+Y505H</td>
<td>Authentic Virus</td>
<td>12* to 30 - fold reduction in susceptibility</td>
<td></td>
</tr>
</tbody>
</table>

* Assay used parenteral antibodies

- Discussions ongoing regarding implications
- The terms of the authorization have not been changed at this time.
PAXLOVID™ Authorization for Treatment

• Nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use
• Nirmatrelvir is a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor.

**Authorization:** for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
PAXLOVID™ – Clinical Considerations

• Drug-drug interactions with CONTRAINDICATIONS for co-administration with some drugs highly dependent on CYP3A for clearance and some potent CYP3A inducers
• Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min)
• Not recommended for patients with severe renal impairment (eGFR < 30mL/min)
• Not recommended for patients with severe hepatic impairment (Child-Pugh Class C)
• Consider risk of development of HIV-1 resistance to protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

Health Care Provider Fact Sheet: https://www.fda.gov/media/155050/download
Molnupiravir Authorization for Treatment

- Molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis.

**Authorization:** for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
Molnupiravir – Clinical Considerations

• Not recommended for use during pregnancy (embryo-fetal toxicity)
• Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose. Pregnancy Surveillance Program: https://pregnancyreporting.msd.com/
• Breastfeeding is not recommended during treatment and for 4 days after the last dose.
• Non-clinical studies to fully assess the potential to affect offspring of treated males have not been completed (if sexually active with individual of childbearing potential, contraception advised during treatment and for at least 3 months after the last dose).
• Not authorized for use in patients less than 18 years of age (may affect bone and cartilage growth)
• Counseling and documentation requirements for prescribers

Health Care Provider Fact Sheet: https://www.fda.gov/media/155054/download
Allocation & Distribution of COVID-19 Therapeutics
Colin W. Shepard, MD
COVID-19 Therapeutics – Update from ASPR

Colin Shepard, MD
Medical Officer
U.S. Department of Health and Human Services (HHS)
CDC Liaison to the Office of the Assistant Secretary for Preparedness and Response, HHS

January 8, 2022

Unclassified/For Public Use
These medications are not a substitute for vaccination.
Federal Support of COVID-19 Therapeutics

FDA
- Reviews Product Application
- Issues EUA
- Reviews Serious Adverse Events
- Develops Patient and Provider Fact Sheets

CDC
- Prepares Clinical Guidelines
- Monitors Variants
- Tracks Case Rates
- Prepares Vaccination Guidelines

HHS/DOD
- Coordinates Distribution
- Facilitates Administration
- Increases Product Understanding and Awareness
- Tracks Use of USG-supplied Products

NIH
Issues clinical guidelines for COVID-19 treatment
CMS/HRSA
Manages reimbursement

State and Territorial Agencies
Facilitate distribution and administration
Distribution and Utilization Summary

4.11M Shipped through all Tx programs

12,298 Number of sites shipped to

2.62M Total reported usage

63.7% % of distributed supply used

1. Total for entire period  2. Total usage as reported since 12/29  3. Reported through date 12/29

Note: Number of sites, % of total stock on hand and total reported usage is updated weekly

Source: ABC Distribution reports, TeleTracking, State Reports
Current Distribution Process: State/Territory-Coordinated System

- State/territory-coordinated distribution system helps maintain equitable distribution, both geographically and temporally—providing states and territories with consistent, fairly-distributed supply over the coming weeks and while the USG works to procure additional supply
- Administration sites no longer order directly from the distributor
- USG determines weekly distribution amounts to states and territories
- State/Territorial Health Departments determine where product goes in their jurisdictions

USG determines weekly distribution amounts; states/territories identify receiving sites and allocate amounts
Stages of COVID-19 Therapeutics

Outpatient

PrEP

No Illness

Exposed
Per CDC Close Contact Criteria

COVID-19 VACCINES
mAbs for PrEP
• Tixagevimab + cilgavimab (AZ)

mAbs for PEP
• Casirivimab + imdevimab (RGN)
• Bamlanivimab + etesevimab (Lilly)

mAbs for treatment
• Bamlanivimab + etesevimab (Lilly)
• Casirivimab + imdevimab (RGN)
• Sotrovimab (GSK/Vir)

Oral antivirals
• Molnupiravir (Merck)
• Paxlovid (Pfizer)

Therapy

COVID ++
Mild to Moderate Symptoms

Hospital Admission

ICU Admission

Inpatient

Exposed

Hospital Admission

ICU Admission

Remdesivir

Tocilizumab

Dexamethasone

Baricitinib

Allocation of bam/ete and REGEN-COV has resumed nationally as of 12/31/2021, see PHE.gov.

The Omicron variant is not neutralized by bam/ete or REGEN-COV.
January Allocation Schedule

- For planning purposes only
- HHS assesses COVID-19 data on a daily basis and may adjust allocation schedule as required

**Jan 10:**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV
Molnupiravir, Paxlovid

**Jan 18**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV

**Jan 24**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV
Molnupiravir, Paxlovid

**Jan 31**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV
About this Week’s Allocations

- Approximately 200,000 (197,386) courses of COVID-19 therapeutics have been allocated to jurisdictions for the period of Jan 3-9, 2022:
  - Sotrovimab (GSK) – 48,498 courses
  - Evusheld (AstraZeneca) – 49,896 courses
  - Bam/Ete (Lilly) – 44,520 courses
  - REGEN-COV (Regeneron) – 54,472 courses

- Monoclonal antibodies now allocated on one-week cycles (for at least the next three weeks); next allocation Monday, Jan 10.

- During the one-week allocation cycles, Sotrovimab and Evusheld WILL NOT be swept at the end of each week – no Federal Pool for additional product requests

- Subsequent allocations will be added to product on hand to increase jurisdictional flexibility

- Oral antivirals on two-week allocation cycle; next allocation Monday, Jan 10

One-week cycle for mAbs; Two-week Cycle for Oral Antivirals
Oral Antiviral Journey | Overview of how drug goes from manufacturer to patient

These therapies require a prescription by a licensed and authorized provider. Patients should coordinate with their healthcare provider prior to contacting a location to receive these therapies.
Update: Allocation of bam/ete and REGEN-COV

- Federal guidance updated Friday, Dec 31, 2021 - all states and territories can continue to order both bam/ete and REGEN-COV based on allocated amounts for clinically appropriate use.

- A number of alternative therapeutics available, including oral and IV antivirals, that are effective against the Omicron variant.
  - NOTE: NIH recommended IV Remdesivir for therapy consideration in outpatients.

- If Delta variant represents significant proportion of infections in a region and other options are not available or are contraindicated, eligible patients can be offered bam/ete or REGEN-COV, with the understanding that these treatments would be ineffective if patients are infected with Omicron.
  - Concern can be mitigated if virus-specific diagnostic testing\(^1\) in a given patient indicates infection with the Omicron VOC is unlikely.

- Dec 30, 2021 National Institutes of Health (NIH) clinical guidelines.
USG-procured mAbs are provided at no cost

• Administration fees for mAbs may be billed by sites.

• CMS reimbursement rates increased:
  • $450 for most outpatient settings.
  • $750 when administered in patient's home.

• Additional information on reimbursement: 
  Monoclonal Antibody COVID-19 Infusion | CMS

• Reimbursement options for uninsured individuals: HRSA
Patient Prioritization Guidance for Treatment

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

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

Last Updated: December 23, 2021
COVID-19 Outpatient Therapeutics Decision Guide

Consider one of the following therapeutics, if available¹,²:
- **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
  - OR
  - sotrovimab 500 mg IV within ASAP 10 days of symptom onset (sotrovimab EUA)
  - OR
  - Remdesivir 200mg IV x 1 dose on day 1, 100mg IV x1 on days 2-3 begun ASAP and within 7 days of symptom onset²

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

**Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant³**

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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.
²Remdesivir 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)
³COVID-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)

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December 30, 2021
Clinical Implementation Guide

Federal Response to COVID-19: Therapeutics Clinical Implementation Guide

- Updated periodically with EUA changes.
- PHE.gov/COVIDTherapeutics

Side-by-Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19

Please contact COVID19Therapeutics@hhs.gov with any questions.
Weekly Stakeholder Engagements

- **Office Call**: Discussion with FRPTP Participants (Pharmacy Group)
  - Tuesdays (12:00–12:30PM ET)

- **Office Call Sessions**: HHS/ASPR Distribution and Administration of COVID-19 Therapeutics—open to all with equity in the process
  - Tuesdays and Thursdays (2:00–2:30PM ET)

- **Stakeholder Call**: State, Local, Tribal, and Territorial Health Officials
  - Wednesdays (2:00–3:00PM ET)

- **Stakeholder Call**: National Healthcare and Medical Orgs and Associations
  - Wednesdays (3:15–4:15PM ET)

- **Federal COVID Response: Therapeutics 210 Webinar**
  - For new administration sites, health officials: Every other Friday (12:00–1:00PM ET)
  - [https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaWltejYzZz09](https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaWltejYzZz09)

Please email COVID19Therapeutics@hhs.gov to request Zoom links for these calls.
COVID-19 Therapeutics for Non-Hospitalized Patients: What Treatments are Preferred – and Why?
Rajesh Gandhi, MD, FIDSA

Disclosures (past 2 years): Member, NIH & Infectious Diseases Society of America COVID-19 Treatment Guidelines Panels; Recommendations in this talk are my own and not necessarily those of the Panels

Acknowledgments: Arthur Kim, Jon Li, Annie Luetkemeyer, Alison Han, Safia Kuriakose, Alice Pau, Efe Airewele
COVID-19 Treatment Guidelines Updated to Include Oral Therapies (Nirmatrelvir/ritonavir, Molnupiravir) and Remdesivir for High-Risk Non-Hospitalized Patients

Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19

Omicron and Outpatient Therapeutics

>50 amino acid changes; ~30 in spike

- Of mAbs authorized for treatment, only sotrovimab anticipated to be active

Small molecule antivirals target SARS CoV-2 replicase:

- Data from cell cultures: preserved activity of nirmatrelvir/ritonavir, molnupiravir, remdesivir against Omicron

Modified from slide from Dr. Arthur Kim


# How do the therapies stack up?

<table>
<thead>
<tr>
<th>Efficacy (prevention hospitalization or death)</th>
<th>1) Nirmatrelvir/r</th>
<th>2) Sotrovimab</th>
<th>3) Remdesivir</th>
<th>4) Molnupiravir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative risk reduction: <strong>88%</strong></td>
<td>• Relative risk reduction: <strong>85%</strong></td>
<td>• Relative risk reduction: <strong>87%</strong></td>
<td>• Relative risk reduction: <strong>30%</strong></td>
<td></td>
</tr>
<tr>
<td>Absolute risk: 6.3%→0.8%</td>
<td>• Absolute risk: 7%→1%</td>
<td>• Absolute risk: 5.3%→0.7%</td>
<td>• Absolute risk: 9.7%→6.5%</td>
<td></td>
</tr>
<tr>
<td>NNT: 18</td>
<td>• NNT: 17</td>
<td>• NNT: 22</td>
<td>• NNT: 31</td>
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</table>

**Pros**
- Highly efficacious
- Oral regimen
- Ritonavir studied (safe) in pregnancy
- Highly efficacious
- Monoclonals typically safe in pregnancy
- Few/no drug interactions
- Highly efficacious
- Studied in pregnancy
- Few/no drug interactions
- Oral regimen
- Not anticipated to have drug interactions

**Cons**
- Drug drug interactions
- Requires IV infusion followed by 1 hour observation
- Requires IV infusion on 3 consecutive days
- Low efficacy
- Concern: mutagenicity
- Not recommended in pregnancy/children
# Bringing it All Back Home: Outpatient Treatment Options for COVID-19

<table>
<thead>
<tr>
<th>Option</th>
<th>Patient Population</th>
</tr>
</thead>
</table>
| Nirmatrelvir/ritonavir| • Patient not on interacting medications  
                         • As soon as possible and within 5 days of symptom onset                        |
| Sotrovimab           | • Patient on interacting medication/able to come to health care facility  
                         • As soon as possible and within 10 days of symptom onset                       |
| Remdesivir           | • Patient in health care facility or through home infusion service  
                         • As soon as possible and within 7 days of symptom onset                         |
| Molnupiravir         | • Patient not able to be treated with one of the options above  
                         • Not pregnant (if given during pregnancy, shared decision making)  
                         • As soon as possible and within 5 days of symptom onset                        |
How do we manage mismatch between supply and demand?

- Massachusetts allocation for 1st week:
  - 1100+ courses of nirmatrelvir/rtv
  - 8000+ courses of molnupiravir
- Prioritize highest risk patients until supply catches up with demand
- Monitor distribution to ensure equitable access
- When supply constraints ease, expand treatment to encompass broader range of patients
<table>
<thead>
<tr>
<th>Tier</th>
<th>Risk group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Immunocompromised individuals regardless of vaccine status or Unvaccinated individuals age ≥75 y or age ≥65 y with additional risk factors*</td>
</tr>
<tr>
<td>2</td>
<td>Unvaccinated individuals age ≥65 y or age &lt;65 y with risk factors*</td>
</tr>
<tr>
<td>3</td>
<td>Vaccinated individuals age ≥75 y or age ≥65 y with additional risk factors*</td>
</tr>
<tr>
<td>4</td>
<td>Vaccinated individuals age ≥65 y or age &lt;65 y with risk factors*</td>
</tr>
</tbody>
</table>

*Risk factors for progressing to severe COVID include advanced age, cancer, cardiovascular disease, chronic kidney disease, chronic lung disease, diabetes, immunocompromised, obesity, pregnancy, sickle cell disease, other conditions*

Future Directions in Outpatient COVID-19 Therapy

• What is the benefit of therapies in lower risk patients (vaccinated, infected with Omicron)?

• Will monotherapy select for viral resistance? Role of combination Rx?
  □ Concern greatest for severely immunocompromised.

• Should these oral therapies, mAbs be used in hospitalized patients?
  Only if patient admitted for non-COVID reason and otherwise meets EUA criteria

• Does early treatment prevent long COVID?
<table>
<thead>
<tr>
<th>Need</th>
<th>Perfect Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>✔️ ✔️ ✔️</td>
</tr>
<tr>
<td>Ease of delivery</td>
<td>✔️ ✔️ ✔️</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>✔️ ✔️ ✔️</td>
</tr>
<tr>
<td>Safety during pregnancy</td>
<td>✔️ ✔️ ✔️</td>
</tr>
<tr>
<td>Authorized in children (&gt;12)</td>
<td>✔️ ✔️ ✔️</td>
</tr>
<tr>
<td>Supply/Access</td>
<td>✔️ ✔️ ✔️</td>
</tr>
</tbody>
</table>

*Remdesivir approved for children >age 12 years and >40 kg; authorized for children under age of 12 years (3.5 to 40 kg)*
### Desiderata: “Things Wanted or Needed”

<table>
<thead>
<tr>
<th>Need</th>
<th>Nirmatrelvir</th>
<th>Sotrovimab</th>
<th>Remdesivir</th>
<th>Molnupiravir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>✓✓✓</td>
<td>✓✓</td>
<td>✓✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ease of delivery</td>
<td>✓✓✓</td>
<td>X</td>
<td>XXX</td>
<td>✓✓✓</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>XXX</td>
<td>✓✓</td>
<td>✓✓</td>
<td>✓✓</td>
</tr>
<tr>
<td>Safety during pregnancy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>XXX</td>
</tr>
<tr>
<td>Authorized in children (&gt;12)</td>
<td>✓✓</td>
<td>✓✓</td>
<td>✓✓✓*</td>
<td>XX</td>
</tr>
<tr>
<td>Supply/Access</td>
<td>XXX</td>
<td>XXX</td>
<td>✓</td>
<td>XX</td>
</tr>
</tbody>
</table>

*Remdesivir approved for children >age 12 years and >40 kg; authorized for children under age of 12 years (3.5 to 40 kg)*

**Conclusion: We Don’t Yet Have the Perfect Drug**
Updates to IDSA Guidance: Early Treatment and Prophylaxis (PReP)
Lindsey R. Baden, MD

Disclosures: Member IDSA Guideline Committee, Chair FDA Antimicrobial Drug Advisory Committee, NIH funded to conduct SARS-CoV-2 Countermeasure Research (vaccines, treatments)
Tixagevimab/cilgavimab (Evusheld™)

• Recommendation (NEW): In moderately or severely immunocompromised individuals* at increased risk for inadequate immune response to COVID-19 vaccine or for whom COVID-19 vaccine is not recommended due to a documented serious adverse reaction to the vaccine, the IDSA guideline panel suggests pre-exposure prophylaxis with tixagevimab/cilgavimab rather than no tixagevimab/cilgavimab.
  • (Conditional recommendation, Low certainty of evidence)

• Remarks:
  • Dosing for tixagevimab/cilgavimab is 150 mg of tixagevimab & 150 mg of cilgavimab administered as two separate consecutive intramuscular injections once.
  • Local SARS-CoV-2 variant susceptibility should be considered.

IDSA Updated 24Dec2021
Sotrovimab (Xevudy™)

• Recommendation 17: Among ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease, the IDSA guideline panel suggests bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab rather than no neutralizing antibody treatment.
  • (Conditional recommendation, Moderate certainty of evidence)

• Remarks:
  • Dosing for sotrovimab is 500 IV once.
  • Patients with mild to moderate COVID-19 who are at high risk of progression to severe disease admitted to the hospital for reasons other than COVID-19 may also receive bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab.
  • Local variant susceptibility should be considered in the choice of the most appropriate neutralizing antibody therapy. Local availability of different monoclonal antibody combinations may be affected by predominance of local variants.
Remdesivir (Veklury™)

• Recommendation (NEW): Among ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease, the IDSA guideline panel suggests remdesivir initiated within seven days of symptom onset rather than no remdesivir.
  • (Conditional recommendation, Low certainty of evidence)

• Remarks:
  • Dosing for remdesivir is 200 mg on day one followed by 100 mg on days two and three.
  • Patients with mild to moderate COVID-19 who are at high risk of progression to severe disease admitted to the hospital for reasons other than COVID-19 may also receive remdesivir.
Nirmatrelvir/ritonavir (Paxlovid™)

• Recommendation (NEW): In ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease, the IDSA guideline panel suggests nirmatrelvir/ritonavir initiated within five days of symptom onset rather than no nirmatrelvir/ritonavir.
  • (Conditional recommendation, Low certainty of evidence)

• Remarks:
  • Patients’ medications need to be screened for serious drug interactions (i.e., medication reconciliation). Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.
  • Dosing based on renal function:
    • Estimated glomerular filtration rate (eGFR) > 60 ml/min: 300 mg nirmatrelvir/100 ritonavir every 12 hours for five days
    o eGFR ≤60 and ≥30 mL/min: 150 mg nirmatrelvir/100 mg ritonavir every 12 hours for five days
    o eGFR <30 mL/min: not recommended
  • Patients with mild to moderate COVID-19 who are at high risk of progression to severe disease admitted to the hospital for reasons other than COVID-19 may also receive nirmatrelvir/ritonavir.
Molnupiravir (Lagevrio™)

• Recommendation (NEW): In ambulatory patients (≥ 18 years) with mild to moderate COVID-19 at high risk for progression to severe disease who have no other treatment options*, the IDSA guideline panel suggests molnupiravir initiated within 5 days of symptom onset rather than no molnupiravir.
  • (Conditional recommendation, Low certainty of evidence)

• Remarks:
  • Patients who put a higher value on the putative mutagenesis, adverse events or reproductive concerns, and a lower value on the uncertain benefits, would reasonably decline molnupiravir.
  • Molnupiravir 800 mg for 5 days.
  • Patients with mild to moderate COVID-19 who are at high risk of progression to severe disease admitted to the hospital for reasons other than COVID-19 may also receive molnupiravir.
  • Molnupiravir is not authorized under the FDA EUA for use in patients < 18 years, because it may affect bone and cartilage growth.
  • Molnupiravir is not authorized under the FDA EUA for pre-exposure or post- exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to COVID-19, because benefit of treatment has not been observed in individuals when treatment is started after hospitalization due to COVID-19.
COVID-19 Therapies for Children
Kathryn M. Edwards, MD

Disclosures:
Dr. Edwards has disclosed the following financial relationships. Any real or apparent conflicts of interest related to the content of this presentation have been resolved.

<table>
<thead>
<tr>
<th>Affiliation / Financial Interest</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant Recipient</td>
<td>CDC (Vaccine Safety with COVID vaccines)</td>
</tr>
<tr>
<td>Grant Recipient</td>
<td>NIH (Mentoring young investigators in vaccine sciences)</td>
</tr>
<tr>
<td>Consultant</td>
<td>BioNet (pertussis vaccines)</td>
</tr>
<tr>
<td>Consultant</td>
<td>IBM (vaccine safety networks)</td>
</tr>
<tr>
<td>Consultant</td>
<td>Data Safety and Monitoring Boards: Sanofi, X-4 Pharma, Seqirus, Moderna, Pfizer, Merck, GSK, Roche</td>
</tr>
</tbody>
</table>
Summary of available SARS-CoV-2 monoclonal antibody preparations based on indication and age/weight inclusion criteria in children and adolescents at high risk for progressing to severe COVID-19

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Minimum Age &amp; Weight</th>
</tr>
</thead>
</table>
| Treatment Mild to Moderate COVID-19 | 1 kg and <40 kg  
  - Bamlanivimab/Etesevimab  
  **>12 years and >40 kg**  
  - Casirivimab/Imdevimab  
  - Sotrovimab | >40 kg  
  - Bamlanivimab/Etesevimab |
| POST- Exposure Prophylaxis     | 1 kg and <40 kg  
  - Bamlanivimab/Etesevimab | >40 kg  
  - Bamlanivimab/Etesevimab  
  **>12 years and >40 kg**  
  - Casirivimab/Imdevimab |
| PRE- Exposure Prophylaxis      | <12 years and <40 kg  
  - No mAb option | **>12 years and >40 kg**  
  - Tixagevimab and Cilgavimab |
Which children and adolescents are considered “high risk” and may qualify for outpatient treatment with SARS-CoV-2 monoclonal antibodies?

- Body mass index (BMI) ≥85th percentile for age and gender
- Immunosuppressive disease or receipt of immunosuppressive therapies
- Neurodevelopmental disorders (e.g., cerebral palsy, trisomy 21)
- A medical-related technological dependence that is not related to COVID-19 (e.g., tracheostomy, gastrostomy)
- Sickle cell disease
- Congenital or acquired heart disease
- Chronic lung disease; asthma or other chronic respiratory disease that requires daily medication for control
- Diabetes
- Chronic kidney disease
- Chronic liver disease (e.g., cirrhosis, autoimmune hepatitis)
- Age <1 year
  - More recent data evaluating risk factors for severe COVID-19 in young infants, identified prematurity (gestational age <37 weeks) as a risk factor for severe COVID-19.
Remdesivir Dosing

Children > 40 kg:
200 mg for first day and then 100 mg for days 2 and 3

Children 3.5 kg to 39 kg:
5 mg/kg for first day and then 2.5 mg/kg for days 2 and 3
8.1 Pregnancy

Risk Summary

There are no available human data on the use of nirmatrelvir during pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Published observational studies on ritonavir use in pregnant women have not identified an increase in the risk of major birth defects. Published studies with ritonavir are insufficient to identify a drug-associated risk of miscarriage (see Data). There are maternal and fetal risks associated with untreated COVID-19 in pregnancy (see Clinical Considerations).

PAXLOVID is not authorized for use in pediatric patients younger than 12 years of age or weighing less than 40 kg. The safety and effectiveness of PAXLOVID have not been established in pediatric patients. The authorized adult dosing regimen is expected to result in comparable serum exposures of nirmatrelvir and ritonavir in patients 12 years of age and older and weighing at least 40 kg as observed in adults, and adults with similar body weight were included in the trial EPIC-HR [see Adverse Reactions (6.1), Clinical Pharmacology (12.3), and Clinical Studies (14)].
Pediatrics (Less Than 18 Years of Age) As previously described, animal studies suggest that MOV may affect bone and cartilage growth. Further, COVID-19 is typically associated with a mild disease course in most pediatric patients. All of the mAbs authorized for the treatment of mild-to-moderate COVID-19 include adolescents (patients 12 years of age and older weighing at least 40 kg) in the authorization. A juvenile toxicity study in rats is planned to further inform the safety of MOV in pediatric patients. If MOV is authorized, the Agency and Sponsor are in agreement that MOV not be authorized for use in patients less than 18 years old.
Pharmacologic Considerations

Amy Hirsch Shumaker, PharmD, BCPS, AAHIVP
## Renal Dosing Paxlovid™ (nirmatrelvir/ritonavir)

<table>
<thead>
<tr>
<th>eGFR Range</th>
<th>Nirmatrelvir* Dose</th>
<th>Ritonavir Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>eGFR ≥ 60 mL/min (mild)</td>
<td>300 mg twice daily x 5 days</td>
<td>100 mg twice daily x 5 days</td>
</tr>
<tr>
<td>eGFR &gt; 30 to &lt; 60 mL/min (moderate)</td>
<td>150 mg twice daily x 5 days</td>
<td>100 mg twice daily x 5 days</td>
</tr>
<tr>
<td>eGFR &lt; 30 mL/min (severe)</td>
<td>Paxlovid (nirmatrelvir/ritonavir) not recommended until more information available</td>
<td></td>
</tr>
</tbody>
</table>

* Nirmatrelvir is renally eliminated; Cmax and AUC were 48% and 204% higher in those with severe renal impairment.

Prescriptions should specify the numeric dosage of each active ingredient within Paxlovid™.
Pharmacist Dispensing Instructions for Paxlovid™ with Moderate Renal Impairment

Pharmacist steps:
1) Remove one nirmatrelvir 150 mg dose from morning and evening dose (doses in middle of card)
2) Affix sticker to cover empty blister cavities
3) Repeat steps 1 and 2 for every blister card in carton (5 per carton for 5-day supply)
4) Affix additional sticker over preprinted dosing regimen

https://www.fda.gov/media/155072/download Accessed: 1/6/2022
Drug-Drug Interactions (DDI’s) with Paxlovid™

- Ritonavir-FDA approved as an HIV protease inhibitor
  - Potent inhibitor of CYP3A4, p-glycoprotein
  - Also inhibits CYP2D6, CYP2C19, CYP2C8 and CYP2C9
  - Inducer of CYP1A2, CYP2B6, CYP269, CYP2C19
- Nirmatrelvir is a substrate of CYP3A4

Major potential for drug-drug interactions

<table>
<thead>
<tr>
<th>Drug Interaction Mitigation Strategies</th>
<th>HIV Setting</th>
<th>COVID-19 Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy expert involved</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Medication reconciliation available</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Access to electronic medical record</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Ability to directly consult with prescribers</td>
<td>+++</td>
<td>+</td>
</tr>
</tbody>
</table>

Paxlovid™
Medication Contraindications and Resources

Drugs highly dependent on CYP3A for clearance and subject to increased concentrations

- Alpha1-adrenoreceptor antagonist: 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 pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

Drugs that can speed up the metabolism of nirmatrelvir

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John’s Wort (hypericum perforatum)

Resources:

- [https://www.covid19-druginteractions.org/](https://www.covid19-druginteractions.org/)
- [https://www.hiv-druginteractions.org/](https://www.hiv-druginteractions.org/)
- HIV/Hep C literature
Paxlovid™ DDI’s in Transplant Patients

Transplant Medications

- Tacrolimus levels (monitor when feasible)
- Cyclosporine levels (monitor when feasible)
- Sirolimus levels (avoid concomitant use)

American Society of Transplantation Statement¹

1) Drug monitoring is challenging in outpatient settings
2) Molnupiravir not evaluated and low efficacy
3) Early monoclonal antibody treatment or IV remdesivir may be preferable

Paxlovid™ DDI’s in Cardiology

• Statins
  • Lovastatin-not recommended
  • Simvastatin-not recommended
  Hold all statins x 5 days?

• Antiarrhythmics-not recommended d/t risk of arrhythmias
  • Amiodarone
  • Dronedarone
  • Flecaïnide
  • Propafenone
  • Quinidine

• Clopidogrel-not mentioned in FDA EUA however known interaction in HIV literature
  • Risk of thrombosis s/p stenting; high risk 6 weeks post stent

• Antihypertensives
  • Increased levels of calcium channel blockers

• Increased digoxin levels
Additional* Paxlovid™ DDI’s (*not an exhaustive list)

• Oncology agents
  • Various concerns if drug ends in:
    • -ib
    • -clax
    • -tine

• Systemic corticosteroids
  • Cushing’s syndrome
  • ? Inhaled steroids
  • ? Injectable steroids

• Women’s Health
  • Decreased effectiveness on ethinyl estradiol
  • Counsel on backup non-hormonal method of contraception

• Men’s Health
  • PDE5-no warning for use in ED; warnings on max doses in HIV literature
Q&A/Discussion
CAPT Lauri Hicks, MD

- Slide 6 - https://www.who.int/publications/m/item/enhancing-readiness-for-omicron-(b.1.1.529)-technical-brief-and-priority-actions-for-member-states
- Slide 10 – SARS-CoV-2 Omicron VOC Transmission in Danish Households (medrxiv.org)
- Slide 13 – Clinical Severity of COVID-19 Patients Admitted to Hospitals in Gauteng, South Africa During the Omicron-Dominant Fourth Wave by Waasila Jassat, Salim Abdool Karim, Caroline Mudara, Richard Welch, Lovelyn Ozougwu, Michelle Groome, Nevashan Govender, Anne von Gottberg, Nicole Wolter, DATCOV Author Group, Lucille Blumberg, Cheryl Cohen :: SSRN
- Slide 14 - Omicron daily overview: 30 December 2021 (publishing.service.gov.uk)
  - rapport-omikronvarianten-29122021-ub46 (ssi.dk)
  - Early estimates of SARS-CoV-2 Omicron variant severity based on a matched cohort study, Ontario, Canada | medRxiv
  - https://www.medrxiv.org/content/10.1101/2021.12.10.21267534v1
  - https://www.biorxiv.org/content/10.1101/2021.12.16.472934v1
  - https://www.medrxiv.org/content/10.1101/2021.12.08.21267491v1.full
- Slide 17- SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)
- Slide 19 - https://www.cdc.gov/mmwr/volumes/70/wr/mm7050e1.htm?s_cid=mm7050e1_w
Today’s Links

John Farley, MD, MPH

• Slide 25 - https://covid.cdc.gov/covid-data-tracker/#variant-proportions
• Slide 27 - EVUSHELD™ Health Care Provider Fact Sheet: https://www.fda.gov/media/154701/download
• Slide 30 – PAXLOVID Health Care Provider Fact Sheet: https://www.fda.gov/media/155050/download
• Slide 27 and 32 –Molnupiravir Health Care Provider Fact Sheet: https://www.fda.gov/media/155054/download
• Slide 32 – Pregnancy Surveillance Program: https://pregnancyreporting.msd.com/

Colin Shepard, MD

• Slide 39 – PHE.gov
• Slide 43 – National Institutes of Health (NIH) clinical guidelines
• Slide 44 – Additional information on reimbursement: Monoclonal Antibody COVID-19 Infusion | CMS
  Reimbursement options for uninsured individuals: HRSA
• Slide 45 - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/
• Slide 47 – https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx
  https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/Side-by-Side-Overview-of-mAbs-Treatment.aspx
• Slide 48 - COVID19Therapeutics@hhs.gov

Rajesh Gandhi, MD, FIDSA

  https://www.covid19treatmentguidelines.nih.gov/
Today’s Links

Amy Hirsch Shumaker, PharmD, BCPS, AAHIVP

- Slide 73 - https://www.fda.gov/media/155072/download
- Slide 74 - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8718360/
- Slide 75 - https://www.covid19-druginteractions.org/
  https://www.hiv-druginteractions.org/

Program Links:
- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- RTLN Survey - https://www.surveymonkey.com/r/BFBJ5CK
- Vaccine FAQ: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/
Continue the conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19

We want to hear from you!
Please complete the post-call survey.

Next Call
Saturday, Jan. 22nd

A recording of this call will be posted at
www.id society.org/cliniciancalls
-- library of all past calls now available --

Contact Us:
Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)