Welcome & Introductions

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Monkeypox Update: New Randomized Clinical Trial on Tecovirimat

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Confronting BA.4/BA.5: What Clinicians Can Do

COVID-19 Situation Update

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Outpatient Therapy Update

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U.S. Department of Health & Human Services

Clinician-Focused Strategies to Increase Treatment & Vaccine Uptake

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Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
Monkeypox Update: *New Randomized Clinical Trial on Tecovirimat for Monkeypox*

Timothy Wilkin, MD
A Randomized, Placebo-Controlled, Double-Blinded Trial of the Safety and Efficacy of Tecovirimat for the Treatment of Persons with Human Monkeypox Virus Disease

*Study of Tecovirimat for Human Monkeypox Virus (STOMP)*

SPONSOR: NIH/AIDS CLINICAL TRIALS GROUP
Background

We are experiencing multicountry outbreak of human monkeypox virus (HMPXV)

Disease is often spread sexually with rectal, genital and oral ulcers occurring commonly

Pain due to proctitis is a new feature and particularly common

Tecovirimat is a promising treatment for HMPXV disease
  ◦ Indicated for the treatment of human smallpox disease
  ◦ Works by inhibiting viral p37 protein (highly conserved in orthopoxviruses) and blocks its interaction with cellular Rab9 GTPase and TIP47, preventing the formation of egress-competent enveloped virions
  ◦ Safety and efficacy data are lacking for HMPXV

Tecovirimat is being used through CDC EA-IND and community demand for treatment is high
Other tecovirimat studies for HMPXV

PALM-007: randomized, double-blind, controlled trial of tecovirimat for HMPXV to be conducted in the Democratic Republic of Congo (n=450)
  ◦ Patients hospitalized for duration of treatment; different clade than current epidemic

PLATINUM: a randomized, double-blind controlled trial of tecovirimat for HMPXV to be conducted in the UK (n=500)
  ◦ Conducted remotely

Canadian trial (details unknown)

WHO/ANRS trial: 6 yrs and old; platform trial; time to complete resolution

All trials are evaluating same dose of tecovirimat, sampling of various compartments for HMPXV
  ◦ Unique features of A5418 rectal sampling, cross-over to tecovirimat for progression or severe pain, 2:1 allocation ratio, enrollment of presumptive HMPXV, earlier in course of disease, structure pain assessment
Study Summary

| Design and Sample size | 2:1 Randomized, Blinded, Placebo-controlled (n=530)  
Intensively sampled subset (n=100)  
Open label for children, persons with pregnancy or severe disease, severe immune suppression or severe skin disease (n≈250) |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Study Population</td>
<td>Symptomatic HMPXV infection (greater than 3 kg)</td>
</tr>
<tr>
<td>Design</td>
<td>Superiority</td>
</tr>
<tr>
<td>1° Outcome</td>
<td>Time to clinical resolution</td>
</tr>
<tr>
<td>Duration</td>
<td>57 days</td>
</tr>
<tr>
<td>Enrollment period</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Agent</td>
<td>Weight based oral Tecovirimat</td>
</tr>
</tbody>
</table>
Hypothesis

Tecovirimat will lead to faster clinical resolution of HMPXV disease compared to placebo.

1° Objective

To compare time to clinical resolution between people with HMPXV randomized to tecovirimat or placebo.

and endpoint

Clinical resolution is when all skin lesions are scabbed over, desquamated, or healed and all visible mucosal lesions healed

Step 1: daily self skin checks and photographs
Step 2: participant reports clinical resolution
Step 3: video visit to confirm clinical resolution
Step 4: confirmation at in person visit
Outpatients (> 3 kg) with:

- **Confirmed or presumptive** disease (oral, rectal, or skin lesion)
  - Presumptive diagnosis with compatible skin or mucosal lesions or proctitis in cisgender men or transgender women with sexual contact with 1 or more cismen or transwomen in 14 days prior to symptom onset or people with exposure to another person with known HMPXV.

- Onset of symptoms of HMPXV infection ≤14 days prior to randomization,

- At least one active, (not yet scabbed) skin lesion, mouth lesion or proctitis with or without visible ulcers

Randomization restricted to those 18 years or older without one of the following conditions

Those with severe disease (ocular involvement, hospitalization, deep lesions requiring surgical intervention, potentially disfiguring lesions on the face), pregnant and breastfeeding people, and those with severe immunodeficiency, severe inflammatory skin conditions, children are in open-label cohort.
Objectives

To compare pain scores between randomized arms.

To compare rates of progression to severe HMPX disease between randomized arms.

To compare clearance of HMPXV between randomized arms in various compartments including blood, skin lesions, oropharynx, rectum, and genital secretions.

To compare time to complete lesion healing between randomized arms.

To compare participant-reported outcomes including adherence and EQ-5D-5L between randomized arms.

To evaluate the safety of tecovirimat as compared to placebo.

To describe time to lesion resolution, pain, clearance of HMPXV, time to complete lesion healing, participant-reported outcomes, and safety of tecovirimat in participants who receive open-label tecovirimat.

To determine the steady-state tecovirimat $\text{AUC}_{0-12h}$ and $C_{12}$ in children less than 18 years of age.

To evaluate the safety profile of 14 days of tecovirimat in children less than 18 years of age.
Schedule of Evaluations

**Tecovirimat or Placebo**

- **Tecovirimat**
  - d<sub>1</sub>
  - d<sub>8</sub>
  - d<sub>15</sub>
  - d<sub>22</sub>
  - d<sub>29</sub>

- **Exam, Swabs, Blood**

- **STI Screen**

- **d<sub>57</sub>**

**Arms A+B**

**Arm C**

Study Diary every day thru Day 29
Lesion self-assessment, Pain Scale, Eq-5d-5L

Daily reminder for diaries

Modified schedule for those <18 years of age

Randomized arm can move to open label tecovirimat for disease progression or severe pain (day 5 or later)
Timeline

1st protocol team meeting: 21JUL2022
Rough draft to FDA: 25JUL2022
Near final draft for FDA pre-review: 02AUG2022
DAIDS CSRC review: 04AUG2022
Submission to FDA/IRB: 11AUG2022
1st person/1st visit: 19SEP2022
COVID-19 Situation Update

Jay Butler, MD
COVID-19 Situation Update
COVID-19 Update

Daily Update for the United States

**Cases**
- New Cases (Daily Avg): 117,350

**Deaths**
- New Deaths (Daily Avg): 377

**Hospitalizations**
- New Admissions (Daily Avg): 6,113

**Vaccinations**
- % First Booster Dose: 34.4%

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**Time period:** 7 day moving average (July 29 – August 4)

**Source:** [CDC COVID Data Tracker: Home](https://covid.cdc.gov/covid-data-tracker/)
Daily Trends in Number of COVID-19 Cases in the US Reported to CDC
Daily Trends in Number of COVID-19 Deaths in The US Reported to CDC
New Admissions of Patients with Confirmed COVID-19, United States

Aug 01, 2020 - Aug 02, 2022

5,078,893
Total Admissions
Aug 01, 2020 - Aug 02, 2022

6,112
Current 7-Day Average
Jul 27, 2022 - Aug 2, 2022

6,396
Prior 7-Day Average
Jul 20, 2022 - Jul 26, 2022

21,525
Peak 7-Day Average
Jan 09, 2022 - Jan 15, 2022

-4.4%
Percent change from prior 7-day avg. of Jul 20, 2022 - Jul 26, 2022

-71.6%
Percent change from peak 7-day avg. of Jan 09, 2022 - Jan 15, 2022

Based on reporting from all hospitals (N=5,530). Due to potential reporting delays, data reported in the most recent 7 days (as represented by the shaded bar) should be interpreted with caution. Small shifts in historic data may occur due to changes in the CMS Provider of Services file, which is used to identify the cohort of included hospitals. Data since December 1, 2020 have had error correction methodology applied. Data prior to this date may have anomalies that are still being resolved. Note that the above graphs are often shown on different scales. Data prior to August 1, 2020 are unavailable.

Last Updated: Aug 04, 2022
New Admissions of Patients with Confirmed COVID-19, United States, Aug 1, 2020 - Aug 2, 2022

National Forecast New Hospitalization Admissions

[Graph showing the forecast of new hospital admissions with reported and ensemble data, along with inner and outer bands for 50% and 95% prediction intervals.]
National Forecast - Deaths

Combined Forecast
- Reported
- Ensemble

New Weekly Deaths

Total Deaths

Inner Bands: 50% Prediction Intervals
Outer Bands: 95% Prediction Intervals
Role of Clinicians to Prevent the Spread of COVID-19

- Vaccination
- Stay aware of COVID-19 community levels
- Continue to educate patients
- Stay up-to-date on guidance
- Protect yourselves
COVID-19 Vaccines
Primary Series Completion, Booster Dose Eligibility, and Booster Dose Receipt by Age, United States

5-11 Years
US Pop: 28,744,900
- Fully Vaccinated: 30.1% (8.66M)
- 1st Booster Eligible: 26.6% (7.64M)
- 1st Booster Received: 3.3% (948k)

12-17 Years
US Pop: 25,304,508
- Fully Vaccinated: 60.1% (15.2M)
- 1st Booster Eligible: 58.3% (14.8M)

18-49 Years
US Pop: 139,763,772
- Fully Vaccinated: 69.0% (96.4M)
- 1st Booster Eligible: 67.8% (94.7M)
- 2nd Booster Eligible: 45.3% (28.8M)
- 2nd Booster Received: 42.8% (27.3M)

50-64 Years
US Pop: 63,659,835
- Fully Vaccinated: 82.1% (52.3M)
- 1st Booster Eligible: 80.6% (51.3M)
- 2nd Booster Eligible: 10.6% (6.73M)
- 2nd Booster Received: 42.8% (27.3M)

65+ Years
US Pop: 54,792,026
- Fully Vaccinated: 91.8% (50.3M)
- 1st Booster Eligible: 89.1% (48.8M)
- 2nd Booster Eligible: 25.3% (13.8M)
- 2nd Booster Received: 61.1% (33.5M)

**Bivalent Booster Vaccines with Omicron BA.4/5 Component**

**Update: COVID-19 Vaccine Booster Composition**

June 30, 2022

FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) held a virtual meeting on **June 28, 2022**, to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccine booster doses is necessary for the 2022 fall and winter seasons.

A majority of the committee voted in favor of including a SARS-CoV-2 Omicron component in COVID-19 vaccines that would be used for booster doses in the U.S. beginning in fall 2022. In consideration of the committee’s vote and the discussion that took place about the specific SARS-CoV-2 variant to include, and considering the totality of the available evidence, FDA has advised vaccine manufacturers seeking to update their COVID-19 vaccines that they should develop modified vaccines that add an Omicron BA.4/5 component to their current vaccine compositions to create two component (bivalent) booster vaccines.

We expect this coming year, when these modified booster vaccines will be introduced, to be a transitional period. Therefore, we have not advised manufacturers to change the vaccine for primary vaccination, since a primary series with this vaccine provides a base of protection against serious outcomes of COVID-19 caused by circulating strains of SARS-CoV-2.

**Additional Information**

- Memorandum Re: Fall 2022 COVID-19 Vaccine Strain Composition Selection Recommendation

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
2022-2023 Influenza Season Outlook

- Seasonal influenza activity for the past two seasons was low
- It’s not possible to predict which influenza virus is going to be predominant or the timing or intensity of a season
- Many countries are seeing differences in the timing of flu epidemics, and high levels of co-circulation with COVID-19 are again a possibility
- Monitoring for co-circulation of both influenza and SARS-CoV-2 is essential
- CDC is monitoring current global influenza activity and continues to enhance our infrastructure domestically to prepare for whatever situation might arise
Outpatient Therapy Update

Meg Sullivan, MD, MPH
COVID-19 Therapeutics
Current Landscape

Meg Sullivan, MD, MPH
Chief Medical Officer
Administration for Strategic Preparedness & Response

August 6, 2022
### Current Landscape: COVID-19 Preventative Agents & Treatments

#### COVID-19 VACCINES

**Monoclonal Antibodies for PrEP**
- Evusheld (tixagevimab + cilgavimab, AZ)

### Exposed

<table>
<thead>
<tr>
<th>No Illness</th>
<th>Mild to Moderate Symptoms</th>
<th>Hospital Admission</th>
<th>ICU Admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline health status, no infection</td>
<td>Not hospitalized, with limitations</td>
<td>Hosp. no act. medical problems</td>
<td>Hospitalized, high flow oxygen/ non-invasive ventilation</td>
</tr>
<tr>
<td></td>
<td>Not hospitalized, with limitations</td>
<td>Hospitalized, not on oxygen</td>
<td>Hospitalized, mechanical ventilation/ ECMO</td>
</tr>
</tbody>
</table>

#### Oral Antivirals
- **Paxlovid** (nirmatrelvir + ritonavir, Pfizer) – Preferred
- **Lagevrio** (molnupiravir, Merck) – Alternative

#### Monoclonal Antibodies for Treatment
- **Bebtelovimab** (Lilly) – Alternative

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1. *Therapeutic Management of Nonhospitalized Adults With COVID-19*
2. *Therapeutic Management of Hospitalized Adults With COVID-19*

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**Veklury® (remdesivir, Gilead)**

Please see NIH Current Inpatient Therapies (https://www.covid19treatmentguidelines.nih.gov/therapies/)
Utilization Summary of Products Distributed by USG

- December 17, 2021 – July 31, 2022
- Based on 93% of sites reporting as of July 31, 2022
- Product specific national administration data for the above timeframe
- State and territorial specific data now publicly available and updated weekly
- [https://aspr.hhs.gov/COVID-19/Therapeutics/orders/Pages/default.aspx](https://aspr.hhs.gov/COVID-19/Therapeutics/orders/Pages/default.aspx)

<table>
<thead>
<tr>
<th>Therapeutic (currently in use)</th>
<th>Courses Ordered</th>
<th>Courses Administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paxlovid¹</td>
<td>6,238,027</td>
<td>3,361,548</td>
</tr>
<tr>
<td>Lagevrio</td>
<td>2,284,405</td>
<td>512,688</td>
</tr>
<tr>
<td>Bebtelovimab</td>
<td>627,536</td>
<td>383,515</td>
</tr>
<tr>
<td>Evusheld (300mg doses)</td>
<td>808,008</td>
<td>415,053</td>
</tr>
</tbody>
</table>

¹Paxlovid + renal Paxlovid
Evusheld Access Update

• New call line for Evusheld product and ordering information: 1-833-EVUSHLD (833-388-7453)

• Additional pathway established for small volume ordering:
  • For individual providers seeking small quantities of product (1-3 patient courses)
  • OrderEvusheld.com

• Evusheld is available at some Federal Pharmacy Partner locations:
  • Albertsons, including Albertsons, Acme, Jewel-Osco, Pavilions, Randalls, Safeway, Star Market, and Vons
  • CPESN
  • Hy-Vee, including Amber Specialty Pharmacy
  • Managed Healthcare Associates (MHA), including Thrifty White

• Locator tool updates: Central Partners are encouraged to update information for Evusheld providers so that accurate information is reflected in the COVID-19 Therapeutics Locator tool.
The repeat dosage of EVUSHELD in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is **300 mg of tixagevimab and 300 mg of cilgavimab** administered every 6 months, refer to Table 1 below. Repeat dosing should be timed from the date of the most recent EVUSHELD dose.

**Table 1** Dose of 300 mg of Tixagevimab and 300 mg of Cilgavimab

<table>
<thead>
<tr>
<th>Antibody dose</th>
<th>Number of vials needed</th>
<th>Volume to withdraw from vial(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>tixagevimab 300 mg</td>
<td>2 vials</td>
<td>3 mL</td>
</tr>
<tr>
<td>cilgavimab 300 mg</td>
<td>2 vials</td>
<td>3 mL</td>
</tr>
</tbody>
</table>

* 300 mg of tixagevimab and 300 mg of cilgavimab are to be administered as separate, consecutive intramuscular injections

**Table 2** Dose of 150 mg of Tixagevimab and 150 mg of Cilgavimab

<table>
<thead>
<tr>
<th>Antibody dose</th>
<th>Number of vials needed</th>
<th>Volume to withdraw from vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>tixagevimab 150 mg</td>
<td>1 vial</td>
<td>1.5 mL</td>
</tr>
<tr>
<td>cilgavimab 150 mg</td>
<td>1 vial</td>
<td>1.5 mL</td>
</tr>
</tbody>
</table>

* 150 mg of tixagevimab and 150 mg of cilgavimab are to be administered as separate, consecutive intramuscular injections
Updates: Paxlovid
What You Need to Know:

• There is strong scientific evidence that antiviral treatment of outpatients at risk for severe COVID-19 reduces their risk of hospitalization and death.

• The antiviral drugs Paxlovid (ritonavir-boosted nirmatrelvir) and Veklury (remdesivir) are the preferred treatments for eligible adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19.

• Clinicians should consider COVID-19 treatment in non-hospitalized patients who meet all of the following:
  o Test positive for SARS-CoV-2 (with PCR or antigen test, including at-home tests)
  o Have symptoms consistent with mild-to-moderate COVID-19. People with mild COVID-19 experience symptoms such as fever, sore throat, cough, or headache that do not affect the lungs and breathing. People with moderate illness have symptoms that affect the lungs like shortness of breath or difficulty breathing.
  o Are within 5 days of symptom onset for Paxlovid or 7 days of symptom onset for Veklury
  o Have one or more risk factors for severe COVID-19

See: Interim Clinical Considerations for Covid-19 Treatment in Outpatients
Risk factors for severe COVID-19 include:

- **Age over 50 years, with risk increasing substantially at age ≥ 65 years**
- **Being unvaccinated or not being up to date on COVID-19 vaccinations**
- **Specific medical conditions and behaviors**

Some people from racial and ethnic minority groups are at risk of being disproportionately affected by COVID-19 due to many factors, including limited access to vaccines and healthcare. Healthcare providers can consider these factors when evaluating the risk for severe COVID-19 and use of outpatient therapeutics.

CDC MMWR: Kaiser Permanente Southern California
Paxlovid and Hospitalizations


Demographics:
- 5,287 patients ≥ 12 years received 5-day Paxlovid treatment.
- Median age was 61.
- 92% had received at least one COVID-19 vaccine dose; 72.5% received at least 3 doses, 8% unvaccinated.

Key Findings:
- 6 hospitalizations and 39 ED encounters related to SARS-CoV-2 infection.
- Hospitalizations and ED encounters for COVID-19 related illness 5-15 days after Paxlovid dispensation occurred <1% of all patients.
- When administered as an early-stage treatment, Paxlovid might prevent COVID-19–related hospitalization among persons with mild to moderate COVID-19 cases who are at risk for progression to severe disease.

For more information see, Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022
Paxlovid: Clinical Trial and Observational Data

- The benefit of a 5-day treatment course of Paxlovid was demonstrated in the clinical trial that supported the EUA. This study showed that among non-hospitalized, unvaccinated patients at high risk of progression to severe disease, treatment with Paxlovid reduced the risk of hospitalization or death by 88%.

- Observational data, including vaccinated patients, from Israel\(^1\), United States\(^2\), and Hong Kong\(^3\) is consistent with benefit in high-risk patients:
  - 67\% reduction in hospitalizations and 81\% reduction in deaths compared to the untreated for patients over 65\(^1\)
  - 45\% reduction in hospitalization and greater reductions for obese or unvaccinated patients among adult patients\(^2\)
  - 75\% reduction in death compared to non-users\(^3\).

References:
3. Carlos K.H. et al. medRxiv 2022.05.19.22275291; doi: https://doi.org/10.1101/2022.05.19.22275291
Paxlovid Access Update

• In our continued efforts to increase oral antiviral dispensing in vulnerable areas, a new initiative was launched to pre-position Paxlovid in areas of high social vulnerability

  o Goal is to pre-position Paxlovid at provider sites (EDs, physician offices, clinics/urgent cares) in areas of the country that are most vulnerable to COVID-19

  o Beginning August 1 2022, emails were sent to nearly 9000 providers to invite a one-time distribution request of 20 courses of Paxlovid

    ▪ Targeted outreach to sites in counties/parishes with high SVI and low dispensing rates of oral antivirals

• Effort intended to make product more readily available to quickly treat patients in vulnerable communities where they are engaging providers
COVID-19 Rebound After Paxlovid Treatment

- The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public on the potential for recurrence of COVID-19 or “COVID-19 rebound.”

- Paxlovid continues to be recommended for early-stage treatment of mild to moderate COVID-19 among persons at high risk for progression to severe disease.
- Paxlovid treatment helps prevent hospitalization and death due to COVID-19. COVID-19 rebound has been reported to occur between 2 and 8 days after initial recovery and is characterized by a recurrence of COVID-19 symptoms or a new positive viral test after having tested negative.
- A brief return of symptoms may be part of the natural history of SARS-CoV-2 (the virus that causes COVID-19) infection in some persons, independent of treatment with Paxlovid and regardless of vaccination status.
- Limited information currently available from case reports suggests that persons treated with Paxlovid who experience COVID-19 rebound have had mild illness; there are no reports of severe disease.

COVID-19 Rebound After Paxlovid Treatment (cdc.gov)
EUA Update
Pharmacists Authorized to Prescribe Paxlovid Under Certain Conditions

July 6, 2022 – FDA authorized state-licensed pharmacists to prescribe Paxlovid, with certain limitations.

• State-licensed pharmacist may prescribe PAXLOVID for individual patient when:
  o Sufficient information is available to assess renal and hepatic function, such as through access to health records < 12 months old or consultation with HCP in established provider-patient relationship with the individual patient AND
  o Sufficient information is available to obtain comprehensive list of medications that patient is taking to assess potential drug interaction, such as through access to healthcare records, patient reporting of medical history, or consultation with HCP in established provider-patient relationship with the individual patient

• Pharmacists should refer an individual patient for clinical evaluation, if any of following:
  o Sufficient information is not available to assess renal and hepatic function.
  o Sufficient information is not available to assess for a potential drug interaction.
  o Modification of other medications is needed due to a potential drug interaction.
  o Paxlovid is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.
EUA Update (cont’d)  
Pharmacists Authorized to Prescribe Paxlovid Under Certain Conditions

• Patients should provide sufficient information to determine eligibility
  o Health records less than 12 months old, including reports of most recent blood work to review for kidney or liver problems
    ▪ Alternatively, the pharmacist may consult with the patient’s current health care provider
  o A list of medications they are taking, including over the counter medications, to screen for potential harmful interactions

• Individual pharmacies will be reviewing the EUA update and deciding whether this mechanism will be implemented for their pharmacists

• Implementation will take time, is not expected to be universal at all pharmacies, and is not available for all patients
  o Going to primary care physicians, T2T locations, and other centers of primary care are still the best options for individuals to receive a prescription for COVID-19 therapeutics

Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir and ritonavir)
Updates: Bebtelovimab
Bebtelovimab Transition to Commercial Availability

**June 29, 2022** - U.S. Department of Health and Human Services, in coordination with the U.S. Department of Defense, purchased an additional **150,000** doses of bebtelovimab.

- The total U.S. government purchase of bebtelovimab is now **750,000** doses.

- Bebtelovimab is authorized for patients for whom alternative FDA approved or authorized COVID-19 treatment options are not accessible or clinically appropriate

- Distribution of USG supply is expected through the week of August 15<sup>th</sup> at full threshold and August 22<sup>nd</sup> at lower threshold
  - Stock out projections are dependent on ordering activity in coming weeks
  - Lilly/USG are working together to support the availability of bebtelovimab without disruption as USG supply ends
    - Bebtelovimab is on track to be commercially available for purchase **starting the week of Aug 15<sup>th</sup>**
    - States/territories and providers will be eligible to purchase directly through Amerisource Bergen; Lilly is not planning state-specific procurement contracts
    - We will continue to update with additional details as they become available

- As commercial product becomes available, consider leveraging USG supply to fill in gaps for the under and uninsured within your jurisdictions
Updates: Lagevrio
Lagevrio (molnupiravir) Authorization

- Lagevrio (molnupiravir) has been authorized by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 outpatient treatment options approved or 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

- Lagevrio (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 Lagevrio (molnupiravir) belongs (i.e., anti-infectives).

For more information, [FDA Lagevrio Fact Sheet for Providers](#)
Equity and Access
Equity Remains a Top Priority

- Established two additional pathways for product access in vulnerable communities.

- USG focused on enhanced outreach and education efforts
  - Developing grassroots campaign
  - Targeted social media content
  - Updated digital content, including product videos
  - Digital Toolkit for providers and patients
  - Webinars with U.S. Surgeon General
  - Starting this week, targeted outreach and product placement to providers sites in high SVI areas with low dispensing

- States/Territories encouraged to amplify where product is sent in their areas
  - Utilize provider communication networks
  - Post receiving sites on state and local health department websites
  - Partner with hospital associations for message amplification
  - Enlist support of public information officers
CDC MMWR: Dispensing of OAVs for COVID-19 by Zip Code Vulnerability Index


• MMWR Summary
  o There was a substantial increase in the number of dispensing sites located throughout the country, concurrent with new initiatives (eg, T2T, LTC, pharmacy programs)
  o At end of study period, 47% of dispensing sites were located in high-vulnerability zip codes
  o Despite the increase in the number of oral antivirals dispensed during the study period, population-adjusted dispensing rates in high-vulnerability zip codes were substantially lower than those in medium- and low-vulnerability zip codes (using equitable distribution index, EDI)
  o Timely administration of oral antivirals depends on multiple factors, including adequate drug supply and distribution; acceptance of the therapy by health care providers and the public; and patient access to testing, prescriptions, and drug dispensing sites

• USG remains actively focused on improving access and equity; your partnership is needed
• Jurisdictions now have access to EDI dashboard within Tiberius
On the Web:
aspr.hhs.gov

Facebook:
facebook.com/ASPRgov

Twitter:
twitter.com/ASPRgov

Twitter: Dawn O’Connell
twitter.com/HHS_ASPR

Instagram:
instagram.com/ASPRgov/

YouTube:
youtube.com/c/ASPRgov

Flickr:
flickr.com/ASPRgov

LinkedIn:
linkedin.com/showcase/hhs-aspr/
Evusheld Remains Readily Available for Use!

- **FDA authorized** extension to the shelf-life **from 18 months to 24 month** for **specific lots** of the refrigerated AstraZeneca monoclonal antibody therapy, Evusheld.

- Evusheld is effective and can protect some of the most vulnerable in our communities from COVID-19.

- The USG continues targeted outreach and education efforts to help inform providers and empower patients.

- There is still ample supply of Evusheld; providers are encouraged to prescribe Evusheld for eligible patients.

- **NOTE:** Lot #AZ220049 expires on August 31, 2022 and will not have an extended expiration date. We ask that sites use this product in the next few weeks.

### Extended Expiry Dating for Evusheld (Tixagevimab Co-Packaged with Cilgavimab) Authorized under EUA 104

<table>
<thead>
<tr>
<th>Co-Pack Lot Numbers</th>
<th>Labeled Co-Pack Expiration Dates</th>
<th>Extended Co-Pack Expiration Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZ210059</td>
<td>Jul 2022</td>
<td>Jan 31, 2023</td>
</tr>
<tr>
<td>AZ210062</td>
<td>Jul 2022</td>
<td>Jan 31, 2023</td>
</tr>
<tr>
<td>AZ210065</td>
<td>Jun 2022</td>
<td>Dec 31, 2022</td>
</tr>
<tr>
<td>AZ220033</td>
<td>Aug 2022</td>
<td>Feb 28, 2023</td>
</tr>
<tr>
<td>AZ220036</td>
<td>Aug 2022</td>
<td>Feb 28, 2023</td>
</tr>
<tr>
<td>AZ220061</td>
<td>Aug 2022</td>
<td>Feb 28, 2023</td>
</tr>
<tr>
<td>AZ220042</td>
<td>Jul 2022</td>
<td>Jan 31, 2023</td>
</tr>
<tr>
<td>AZ220053</td>
<td>Jul 2022</td>
<td>Jan 31, 2023</td>
</tr>
<tr>
<td>AZ220059</td>
<td>Jul 2022</td>
<td>Jan 31, 2023</td>
</tr>
<tr>
<td>AZ220056</td>
<td>Jul 2022</td>
<td>Jan 31, 2023</td>
</tr>
</tbody>
</table>

Disregard the Component Lot Numbers shared previously. The Co-Pack Lot Numbers (carton Lot Numbers) should be used to identify product affected by the expiry extension.
Paxlovid Shelf-Life Extension

- Upon EUA, Paxlovid was issued a 12-month product shelf-life
- Four lots of Paxlovid manufactured prior to the EUA issuance were labeled with a 9-month expiry
- FDA authorized extended expiration dates for these lots to reflect the 12-month product shelf-life (see Table), when stored according to the storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 105 for Paxlovid.
- This information is now posted on the FDA's website.

<table>
<thead>
<tr>
<th>Lot#</th>
<th>Extended Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>FL4516</td>
<td>The initial 3 lots were extended from 7/31 to 10/31/22.</td>
</tr>
<tr>
<td>FL4517</td>
<td></td>
</tr>
<tr>
<td>FR7229</td>
<td></td>
</tr>
<tr>
<td>FR9088</td>
<td>4th lot was extended from 8/31 to 11/30/22</td>
</tr>
</tbody>
</table>
Did you know: ASPR has new name!

• July 20, 2022 – U.S. Department of Health and Human Services Secretary Xavier Becerra announced the elevation of ASPR from a Staff Division to an Operating Division within HHS.

• Change allows ASPR to mobilize a coordinated national response more quickly and stably during future disasters and emergencies while equipping the organization with greater hiring and contracting capabilities.

• Places ASPR on the same level within HHS as other Operating Divisions within the department such as CDC, FDA and NIH.

New organization name:
Administration for Strategic Preparedness and Response (ASPR)
Clinician-Focused Strategies to Increase Treatment & Vaccine Uptake

Elisa Choi, MD, FACP, FIDSA
Valeria Cantos, MD
Moving past “pandemic fatigue” – Improving outpatient COVID-19 treatment and vaccines/boosters utilization

Elisa Choi, MD, FACP, FIDSA (She/Her)
Internal Medicine, Infectious Diseases
Chair, Board of Governors – American College of Physicians (ACP)
CDC/IDSA COVID-19 Real Time Learning Network Advisory Group

August 6, 2022

@DrElisaChoi
Disclosures

• No financial or IP disclosures

• Views and opinions expressed are my own and do not necessarily represent the official position or policy of organizations with which I am affiliated
Daily Change in the Total Number of Administered COVID-19 Vaccine Doses Reported to CDC by the Date of CDC Report, United States – August 3, 2022

@DrElisaChoi
Daily Trends in Number of New COVID-19 Hospital Admissions in the United States – August 2, 2022

@DrElisaChoi
Trends in COVID-19-Associated Hospitalizations among Adults Ages ≥65 Years – July 2022
ED encounters of COVID-19 patients among vaccination groups – Lancet VOLUME 4, 100065, DECEMBER 01, 2021

@DrElisaChoi
COVID-19 Outpatient Treatment Guidelines Roadmap – CDC/IDSA COVID-19 Real Time Learning Network

This roadmap is not intended to represent a prioritization scheme for therapeutic choices. For information on prioritization of one outpatient treatment over another, see NICE’s guidelines on the therapeutic management of non-hospitalized adults with COVID-19 and APEX Clinical Decision Aid.

@DrElisaChoi
Public Health resources

How to access therapeutic treatments

Call your doctor right away to learn about your treatment options if you are positive for COVID-19. OR

- Telehealth is available for individuals 18 or older living in Massachusetts. Learn more at mass.gov/CovidTelehealth. This is a quick and easy way to see if Paxlovid is right for you. If it is, we’ll arrange for you to pick it up at your local pharmacy or ship it with free overnight delivery.

- Anti-SARS-CoV2 monoclonal antibodies and oral antivirals are available through state-funded sites across the Commonwealth. Click here to find a location near you.

- You may qualify for our in-home treatment program. Visit mass.gov/InHomeCovidTreatments to learn more about eligibility.

View a map of locations offering antiviral pills and monoclonal antibody treatment: MA COVID-19 Therapeutic Locator

Free telehealth for COVID-19 treatment with Paxlovid

In-home COVID-19 Treatment Program

MA COVID-19 Therapeutic Locator (Map)
Public Health resources

COVID-19 treatment with Evusheld

Evusheld (tixagevimab/cilgavimab) is a preventative treatment given by 2 injections at the same visit that helps prevent COVID-19 in individuals whose bodies have trouble making antibodies.

TABLE OF CONTENTS
- Eligibility
- How to access Evusheld
- Information for providers
- Updates
- Related

Eligibility

Evusheld is used before someone gets COVID-19 and is for individuals ages 12 and older who:
- weigh more than 88 pounds
- are not infected with COVID-19
- have a weakened immune system because of a medical condition or medication
- have a history of severe reactions to substances in COVID-19 vaccines

If you received a COVID-19 vaccine, you should wait at least 2 weeks to receive Evusheld.

How to access Evusheld

First, talk to your doctor to see if Evusheld is right for you because a prescription is needed.

Your doctor can help you find a site administering Evusheld by using an in-network referral or by submitting a referral to a partipating site – more details listed below. You may also be eligible for the state’s in-home COVID-19 treatment program.

If you received the initial lower dose of Evusheld that was recommended prior to the U.S. Food and Drug Administration’s Feb. 24 dosage update, talk to your health care provider and schedule to return for an additional 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible.
Nirmatrelvir/Ritonavir (Paxlovid™) Point-of-Care Reference

Nirmatrelvir/ritonavir (brand name Paxlovid™) has been FDA-authorized for emergency use to treat mild-to-moderate COVID-19 since December 2021.

**CLINICAL INFORMATION**

**Eligibility:** The nirmatrelvir/ritonavir FDA-authorized for treatment of adults and pediatric patients 12 years and older weighing at least 65 kg (143 lb) with positive SARS-CoV-2 test results who are at high risk for progression to severe COVID-19. Nirmatrelvir/ritonavir is not recommended for patients with severe renal impairment.

**Dosing:** Nirmatrelvir/ritonavir is dosed in blister packs that contain two 100 mg tablets of nirmatrelvir and one 100 mg tablet of ritonavir. Nirmatrelvir/ritonavir dosing varies by kidney function; as below. In some cases, only one of the nirmatrelvir tablets will be needed (100 mg ritonavir tablet, however, is always given, regardless of renal function).

<table>
<thead>
<tr>
<th>GFR (mL/min)</th>
<th>Dose of nirmatrelvir/ritonavir daily dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;60 mL/min</td>
<td>750 mg nirmatrelvir + 100 mg ritonavir twice daily for 5 days</td>
</tr>
<tr>
<td>60-89 mL/min</td>
<td>500 mg nirmatrelvir + 100 mg ritonavir twice daily for 5 days</td>
</tr>
<tr>
<td>&gt;90 mL/min</td>
<td>Not recommended; appropriate dosing has not been determined.</td>
</tr>
</tbody>
</table>

**Clinical Decision-Making:** In ambulatory patients with mild-to-moderate COVID-19 at high risk for progression to severe disease, ISSA guidelines suggest nirmatrelvir/ritonavir be initiated within 5 days of symptom onset (conditional recommendation; low certainty of evidence). NIT guidelines also suggest nirmatrelvir/ritonavir for nonhospitalized patients with mild-to-moderate COVID-19 who are at high risk of disease progression.

The Real-Time Learning Network’s COVID-19 Outpatient Treatment Guidelines Roadmap (idsa.org/covid-19/therapeutics-clinical-diagnosis) also offers prescribers access to evaluate current U.S. treatment options.


@DrElisaChoi
Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022

Summary
What is already known about this topic?
Lagevrio and Paxlovid are oral antiviral drugs effective at preventing hospitalization and death in patients with mild to moderate COVID-19 who are at risk for progression to severe disease.

What is added by this report?
During December 23, 2021–May 21, 2022, 1,076,762 oral antiviral prescriptions were dispensed in the United States. The overall number of antivirals dispensed increased; however, by the end of the study period, dispensing rates were lowest in high vulnerability zip codes, despite these zip codes having the largest number of dispensing sites.

What are the implications for public health practice?
Additional public health, regulatory, and policy efforts might help decrease barriers to oral antiviral access, particularly in communities with high social vulnerability.
Molnupiravir has been FDA-authorized for emergency use to treat mild-to-moderate COVID-19 among nonhospitalized, nonpregnant adults since December 2021.

**CLINICAL INFORMATION**

**Eligibility:** The molnupiravir ELA covers adults 18 years of age and older who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate. If it is decided to give molnupiravir, treatment should begin as soon as possible after diagnosis and within 5 days of symptom onset.

**Dosing:** A course of molnupiravir consists of 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days.

**Clinical Decision-Making:** In ambulatory adult patients with mild-to-moderate COVID-19 at high risk for progression to severe disease who have no other treatment options, [Pfizer guidelines suggest](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/P233218_P8_FullGDD.pdf) molnupiravir be initiated within 5 days of symptom onset (conditional recommendation, low certainty of evidence). [NICE guidelines](https://www.nice.org.uk/guidance/ng176) also suggest molnupiravir only when other antiviral options cannot be used (class CII recommendation).

Molnupiravir Quick Point-of-Care Reference

SAFETY

Pregnancy: FDA Fact Sheet for Health Care Providers states: “Based on findings from animal reproduction studies, molnupiravir may cause fetal harm when administered to pregnant individuals... therefore, molnupiravir is not recommended for use during pregnancy.”

New COVID-19 Treatment Guidelines states: When other therapies are not available, pregnant people with COVID-19 who are at high risk of progressing to severe disease, particularly those who are beyond the time of embryogenesis (i.e., >15 weeks’ gestation), may reasonably choose molnupiravir therapy after being fully informed of the risks.

FDA and NIAID both recommend that prescribing clinicians should document that a discussion with the patient of the risks and benefits occurred and that the patient chose this therapy after the discussion occurred.

Interactions With Other Therapeutics: No clinical drug-drug interaction studies of molnupiravir have been conducted, but no drug-drug interactions are expected based on available information.

SUPPLY & ACCESS

Distribution: Molnupiravir is currently available in limited quantities in the U.S. and is being allocated by the federal government to health departments in states, territories, and jurisdictions as well as select community health centers.

For allocation details, refer to TMC’s distribution summary. For information intended for health providers, see MDAC COVID–19 Therapeutics Landscape. For patient-facing information, refer to Idals Text-to-Tweet COVID-19 Medications Locator.

CODING, BILLING & REPORTING

Coding

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosage</th>
<th>Package Size</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molnupiravir</td>
<td>200 mg/1</td>
<td>42 capsules in one bottle, plastic</td>
<td>NDC-0593-1555-01</td>
</tr>
<tr>
<td>Molnupiravir</td>
<td>200 mg/2</td>
<td>42 capsules in one bottle, plastic</td>
<td>NDC-0593-1556-07</td>
</tr>
</tbody>
</table>

Billing: Molnupiravir has been added to the Medicaid and Children’s Health Insurance Program formularies as a payable pharmacy benefit.

Reporting: Providers are required to report federally purchased course administration daily by 11:59 p.m. ET via Idals Health Partner Order Portal.

FURTHER INFORMATION

Real-Time Learning Network Molnupiravir Literature Reviews
FDA Molnupiravir: EUA Fact Sheet for Health Care Providers
NIAID Molnupiravir: EUA Fact Sheet for Health Care Providers

Effect of Molnupiravir on Biomarkers, Respiratory Interventions, and Medical Services in COVID-19 – 7 June 2022 Annals of Internal Medicine
COVID-19 “antivirals” virtual visits
“Free telehealth for COVID-19 treatment with Paxlovid”

Free telehealth for COVID-19 treatment with Paxlovid

Telehealth is a quick and easy way to see if Paxlovid, a COVID-19 treatment pill, is right for you. This is a new service provided by the Commonwealth of Massachusetts.

TABLE OF CONTENTS
- Who can take Paxlovid?
- Get a free video consultation
- Covid-19 Treatment Flyers
- Need help?
- Contact
- Related

@DrElisaChoi
Global COVID-19 deaths averted due to vaccination based on excess mortality – Lancet ID June 23, 2022 (DOI: https://doi.org/10.1016/S1473-3099(22)00320-6)
Median deaths averted by vaccinations per 10 000 people by country in the first year of COVID-19 vaccination - Lancet ID June 23, 2022 (DOI: https://doi.org/10.1016/S1473-3099(22)00320-6)

@DrElisaChoi

Summary

What is already known about this topic? COVID-19 vaccination is critical to controlling the COVID-19 pandemic; health care providers play an important role in achieving high vaccination coverage.

What is added by this report? Adults who reported a provider COVID-19 vaccination recommendation were more likely to have been vaccinated; to be concerned about COVID-19; to have confidence that COVID-19 vaccines are important and safe; and to perceive that family and friends had been vaccinated.

What are the implications for public health practice? A health care provider recommendation for COVID-19 vaccines at every visit could increase coverage and confidence in vaccines, particularly among groups with lower COVID-19 vaccination coverage, including younger adults, racial/ethnic minorities, and rural residents.

@DrElisaChoi

A recommendation from a health care provider helps to increase COVID-19 vaccination

Recommendations were associated with more vaccination among adults, including:

- younger adults
- some racial and ethnic minorities
- those living in rural areas
- those who did not have school or work requirements

Talk to your patients about getting vaccinated

bit.ly/mm7050a1

@DrElisaChoi
COVID-19 cases (April 4–December 25, 2021) and deaths (April 4–December 4, 2021)
EHR & Vaccines/Boosters
COVID-19 In-Home Vaccination Program

In-home vaccinations are available for anyone who has difficulty getting to or using a community vaccination location.

TABLE OF CONTENTS
- Eligibility
- How to schedule an in-home vaccination
- Related
How to effectively address misinformation
(https://www.cdc.gov/vaccines/covid-19/health-departments/addressing-vaccine-misinformation.html)
Effect of Outreach From Primary Care Physicians (PCPs) for COVID-19 Vaccination of Black and Latino Older Adults

RCT: Effect of Outreach From Primary Care Physicians (PCPs) for COVID-19 Vaccination of Black and Latino Older Adults

POPULATION
3622 Men, 4665 Women

Black and Latino adults aged ≥65 y
30% aged ≥75 y

INTERVENTION
8267 Patients randomized

2773 Usual care
No additional outreach beyond prior generic outreach given to all groups

2767 Culturally tailored PCP outreach
Culturally tailored electronic messages, letters, and postcards from PCPs

2747 Standard PCP outreach
Electronic messages, letters, and postcards from PCPs

FINDINGS
Culturally tailored PCP outreach and standard PCP outreach led to higher COVID-19 vaccination rates than usual care

COVID-19 vaccination (vs usual care):
Standard PCP outreach: 1.17 (95% CI, 1.04-1.30)
Culturally tailored outreach: ratio, 1.32 (95% CI, 1.09-1.37)

USA 2022; 318(5):e221004. doi:10.1001/jamaoncon2022.07004
COVID-19 Resources – American College of Physicians (ACP)

ACP and YouTube Partner to Combat COVID-19 Misinformation: Two new video series help combat misinformation about COVID-19 and vaccinations, help physicians build vaccine confidence, and answer vaccination-related patient questions. Some videos also available in Spanish!

- Ask Your Internist: Answers vaccination-related patient questions, providing evidence-based information from trusted physician messengers.
- Physician-to-Physician Conversations: Shares practical communication strategies to help physicians and other healthcare professionals build vaccine confidence and address patient concerns that may be rooted in misinformation.

COVID-19 Forums

Presented by The American College of Physicians and Annals of Internal Medicine, these virtual forums feature a panel of experts providing practical information related to what physicians and other health care officials need to know about COVID-19.

- COVID Forum 9: Management of Patients With Persistent Symptoms After COVID-19 5/31/2020
- COVID Forum 8: Outpatient Evaluation and Management of Patients with COVID-19 2/19/2020
- COVID Forum 7: Challenging Clinical Questions 12/14/2020
- COVID Forum 6: Clinical and Public Health Implications of SARS-CoV-2 Immunology 10/13/2020
- COVID Forum 5: Evaluation and Care of Patients With Persistent Symptoms Following Acute SARS-CoV-2 Infection 6/8/2020
- Vaccine Forum 4: Practical Clinical Considerations 3/30/2021
- Vaccine Forum 3: Allocation & Distribution 1/23/2021
- Vaccine Forum 2: Promoting Vaccination 12/31/2020
- Vaccine Forum 1: What Physicians Need to Know 11/17/2020

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COVID-19 Resources – “Ask Your Internist” You Tube (ACP)

@DrElisaChoi
COVID-19 Resources – “Physician to Physician” You Tube (ACP)
Summary (1)

• COVID-19 Therapeutics ➔ access to outpatient treatments

• Primary care and team based care
• population health approaches
• public health resources
• telemedicine platforms
• pharmacy/pharmacists partnership

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COVID-19 Vaccinations ➔ “Treatment is not a substitute for vaccination”

- Primary care physicians & clinicians – trusted “vaccine ambassadors”
- “talk COVID-19 vaccines” at every opportunity/visit
- Rebut “waiting for better vaccine”
- focus on vaccine success vs. severe COVID-19
- Prioritize vaccine ambivalent, minoritized communities, limited English proficiency
- combat misinformation/disinformation with resources & data
- “An ounce of prevention is worth a pound of cure.” – Benjamin Franklin ➔ well-fitted masks, physical distancing
- COVID-19 vaccines = “death prevention”

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References (1)


- COVID-19 Outpatient Treatment Guidelines Roadmap – CDC/IDSA COVID-19 Real Time Learning Network:


- Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022: [https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm](https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm)


@DrElisaChoi
How to effectively address misinformation: https://www.cdc.gov/vaccines/covid-19/health-departments/addressing-vaccine-misinformation.html

Number of Primary Care Physicians (PCPs) per 100 000 Population and COVID-19 Vaccination Rates Across US Counties - JAMA Netw Open. 2022;5(2):e2147920: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2788927


Effect of Outreach From Primary Care Physicians (PCPs) for COVID-19 Vaccination of Black and Latino Older Adults: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793497


COVID-19 Resources – “Ask Your Internist” You Tube (ACP): https://www.youtube.com/playlist?list=PL8cWWG6tbv1PkCWMz8o43xGJ2rpBxRBXa

COVID-19 Resources – “Physician to Physician” You Tube (ACP): https://www.youtube.com/playlist?list=PL8cWWG6tbv1PgMvhDWS2em9RbbyXb9vvn

References (2)
On a positive note…

• “We’ll observe how the burdens braved by humankind
  Are also the moments that make us humans kind;
  Let each morning find us courageous, brought closer;
  Heeding the light before the fight is over.
  When this ends, we’ll smile sweetly, finally seeing
  In testing times, we became the best of beings.”

• April 2020 - Amanda Gorman - ‘The Miracle of Morning’

• https://www.youtube.com/watch?v=XOieGJIl6g4s

@DrElisaChoi
Thank you

• Elisa Choi, MD, FACP, FIDSA (She/Her)

• Twitter: @DrElisaChoi

• Instagram: @drelisachoi

• Facebook: Dr. Elisa Choi, MD, FACP, FIDSA - https://www.facebook.com/DrElisaChoi/

• CDC/IDSA COVID-19 Real Time Learning Network:

  • https://www.idsociety.org/covid-19-real-time-learning-network/

  • Twitter: @RealTimeCOVID19

@DrElisaChoi
Optimizing COVID-19 booster and new therapeutics uptake among minoritized communities: Lessons Learned

Valeria Cantos, MD
Assistant Professor
Division of Infectious Diseases, Emory University
COVID-19 Vaccine First Booster Uptake by Race/Ethnicity

Source: CDC COVID Data Tracker
COVID-19 Vaccine Second Booster Uptake by Race/Ethnicity

Second Booster Doses
(% of fully vaccinated people ages 50 years and older)

Capped at 95%

Oct 2021  Jan 2022  Apr 2022  Jul 2022

Source: CDC COVID Data Tracker
Inequities in medication prescription

FIGURE 3. Courses of oral COVID-19 antiviral therapy dispensed per 100,000 persons, by week and zip code social vulnerability level — United States, December 26, 2021–May 21, 2022*
It’s been 2.5 years...

Clinicians are TIRED

- Increased workload
- Staff shortages and turnover
- Juggling alternative childcare during school closings
- Recurring cycles of COVID-19 urges with new variants

Burnout, compassion fatigue, depression, anxiety, PTSD
It’s been 2.5 years...

Patients are TIRED
- Continuing financial struggles
- Pandemic fatigue
- Ever changing guidelines and recommendations
- Limited awareness of COVID-19 oral antivirals

“How many more shots will I have to take?”

“Do I really need a booster?”
During clinic visits

- Acknowledge patients’ (and your own) hardships and fatigue
- Provide easy to understand information about benefits of boosters, regardless of reason for visit → optimize opportunity for vaccination at every visit
- Avoid shame, blame, scare techniques
- Focus on allowing patients to live their lives, while including risk reduction language
- Include in clinic template notes reminders about COVID-19 vaccination status and due dates for boosters
- Intentionally reach out to patients who belong to minoritized groups to provide direct information about boosters and therapeutics

Sources: Fiscella K, et al, JAMA Health Forum, 2022; WHO
Clinic leadership

• Organize provider’s COVID-19 updates to standardize knowledge

• Track equitable distribution of boosters and therapeutics through the EMR and/or pharmacy orders and make adjustments to process as needed

• **Hire staff that belong to minoritized communities (including in leadership positions)**

• Foster a safe space environment for minoritized communities
  • Honest & visible messaging of not sharing personal health information with immigration authorities

• Make all patient-facing content available in their preferred language

Sources: Fiscella K, et al, JAMA Health Forum, 2022; WHO
With the community...

• **Connect with local trusted CBOs** to create community awareness, indications and mortality benefits of COVID-19 boosters and oral antivirals

• Culturally and linguistically appropriate information

• Important to include ACCESS guidance

Source: Fiscella K, et al, JAMA Health Forum, 2022
With the community...

• Learn from YOUR local minoritized communities
• Understand the main motivators and barriers of the communities you care for related to vaccine uptake

• Limited access to information
• Difficulties with online content
• Limited transportation
• Inability to miss work to attend visits
• Language barriers with clinic staff and providers
• Fear of deportation when accessing services
With the community....

Advocacy: use your privilege as a HCW to shine a light on inequities and advocate for change at the clinic, community, state and federal level
Q&A/
Discussion
Selected Resources

COVID-19 Update: Dr. Butler
• https://covid.cdc.gov/covid-data-tracker/#datatracker-home
• https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions
• https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop
• https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Outpatient Therapy Update: Dr. Sullivan
• https://www.covid19treatmentguidelines.nih.gov/therapies/
• https://aspr.hhs.gov/COVID-19/Terapeutics/orders/Pages/default.aspx
• https://app.smartsheet.com/b/form/21e4312a2985457f982bb2738cf82744
• https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/
• https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/
Outpatient Therapy Update Cont.: Dr. Sullivan

Selected Resources

- https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm?s_cid=mm7125e2_w
- https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7125e2-H.pdf
- https://www.fda.gov/media/155050/download
- https://emergency.cdc.gov/han/2022/pdf/CDC_HAN_467.pdf
- https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Paxlovid/Pages/default.aspx
- https://www.fda.gov/media/155050/download
- https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e1.htm?s_cid=mm7125e1_e&ACSTrackingID=USCDC-921_DM84696&ACSTrackingLabel=This%20Week%20in%20MMWR%20-%20Vol.%2071%2C%20June%2024%2C%202022&deliveryName=USCDC-921_DM84696
- https://www.fda.gov/media/155050/download
- https://www.fda.gov/media/155049/download
Selected Resources

Clinician-Focused Strategies to Increase Treatment & Vaccine Uptake: Dr Choi

- [https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(21)X0005-1](https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(21)X0005-1)
- [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext)
- [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext)
- [https://www.cdc.gov/vaccines/covid-19/health-departments/addressing-vaccine-misinformation.html](https://www.cdc.gov/vaccines/covid-19/health-departments/addressing-vaccine-misinformation.html)

Program Links:

- This webinar is being recorded and can be found with the slides online at [https://www.idsociety.org/cliniciancalls](https://www.idsociety.org/cliniciancalls)
THANK YOU

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

A recording of this call, slides and the answered Q&A will be posted at www.idsociety.org/cliniciancalls
-- library of all past calls available --

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